

Avazzia Pro-Sport II™ & Best-RSI™ Devices



USER'S MANUAL

PRINCIPLES AND PRACTICE
IN THE MANAGEMENT OF ACUTE
AND EXACERBATED CHRONIC PAIN

LEVEL 1

AVAZZIA

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PREFACE

Avazzia, Inc. has set its mission as “The non-pharmaceutical relief of pain”.

The simplicity of BEST™ devices is obvious when one considers the devices are controlled with an “on/off” switch, intensity “up/down” buttons, and a single button to select modes. Avazzia devices are small, operate on two “AA” batteries, and are easy to use.

Pacific Health Options has applied over ten years of biofeedback electro-stimulation clinical experiences and collaboration to develop unique BEST™ treatment protocols to bring a new level of application understanding and effective pain relief.

Medical professionals can quickly learn BEST™ therapy, and individuals are taught to apply the technology at home.

INTRODUCTION

This book was written as an introductory training guide for health professionals who have recently been introduced to Biofeedback Electro Stimulation Technology (BEST™), the Best-RSI™ and Pro-Sport II™ devices. The subject matter contained herein covers the first of three training phases.

In the hands of a skilled practitioner, the BEST™ device is an incredible tool for Biofeedback therapy and pain management. In reality, it is like a paintbrush in the hands of an artist. With the brush one may be capable of painting a *Rembrandt* or only a fence, depending on skill. Effective pain therapy is also art, composed of many sciences, and skill must be acquired to use the brush that is Avazzia BEST™ to its fullest potential. This manual is intended to be a practical, simple to apply, fast to learn text for everyday use in practice of the art of pain management.

Artists use a paint brush for the primary tool of their work. The paint brush functions as a tool for composition, but the finished work is truly an expression of the will and mind of the artist who wields the brush. Great works of art then are expressed by the skill of the artist and by the quality of his or her tools and techniques. Behind the composition of all artistic works there are always human stories, natural histories of technique, subject matters, and ultimately, all that the artist desires for the viewer to consciously or subconsciously experience what he as an artist may be capable of communicating.

Effective pain relief is also an artistic work, a work requiring the acquisition of knowledge to skillfully employ the paint brush that is Avazzia BEST. Students should appreciate the emergence of Avazzia BEST technology as a precious endowment from the past by those who cared about their generation's present and future welfare. Therefore for students to fully appreciate this *amazing paint brush of therapy* that has now become available, it is important they be familiar with the brilliant discoveries and scientific insights that have laid the foundation for its bequeathal.

The pioneers of neuro-therapy are presented to demonstrate the science behind the technology. A brief history of the evolution of neuro stimulation is presented leading up to BEST™ therapy.

In the opening pages of the teaching section, instructions are given on device settings and operation. Definition of modes and their indications are described. An overview into the basic physiology and science of BEST™, which is necessary for the student to understand fully what he or she is affecting and how form and functionality are changed with application, is presented. Pain theory and protocols are covered extensively in the middle sections followed by various specialized techniques. Technique training, as it progresses, focuses narrowly on specific clinical conditions involving special treatment protocols. Finally, formulation of treatment plans and therapeutic strategies conclude the subject of Level 1 training. An appendix and glossary are included at the end with convenient charts that can be utilized as a reference for the practitioner's convenience in the delivery of BEST™ treatment.

The author extends the well-worn admonition to practitioners reading this text that there is no substitute for experience gained from firsthand knowledge in the clinic. Every practitioner will eventually develop his own technique, which will likely be an amalgamation from this manual, many other sources, and his own, gleaned from personal observation and experience. Experimentation is encouraged for maximum therapeutic effect. Psychologically, there is nothing more powerfully re-enforcing to a patient's sense of well-being than hands-on attention by a confident, compassionate practitioner. Advanced techniques will be covered in Level 2 and 3 training.

PIONEERS OF MODERN ELECTRO-STIMULATION TECHNOLOGY



Torpedo Fish

The beginning of electrical stimulation for abating physical pain is lost in antiquity. Early accounts of using torpedo fish and eels to deliver strong electric shocks to the body were known to exist in the Egyptian civilization. Magnetic iron, lodestones, and electrically charged Amber were all known to most ancient peoples.

Galen (AD131-201), the famous Roman physician, records the use of electrical fish to cure gout and other diseases. Electric fish were used in India and the Middle East throughout the middle ages and into the mid 19th century. The eighteenth through the early twentieth century saw the use of Leyden jars and all types of static electricity collecting and discharging devices. Many types of direct current devices were invented and applied to various areas of the human body for a multiplicity of disease conditions.

Nicola Tesla invented the modern transformer and opened the door for the practical application of alternating electricity. Electro-therapy followed suit, developing devices based upon the generation of biphasic alternating electrical wave forms. In Tesla's lifetime, thousands of alternating current devices were deployed by medical practitioners of all genres and mores. Some were effective for their stated purpose, but many were conceived with hucksterism and quackery in mind. To the uneducated public, the medical use of electricity was still a mysterious and magical force. Early twentieth century Hollywood depictions of Frankenstein in the Transylvanian laboratory did little to clarify the legitimate therapeutic application of electricity. The role of bio-electromagnetism, bio-electricity, and the nature of the biological photon and electron was poorly defined and critical concepts established by basic research into cellular and sub cellular physiology necessary for the application of any clinically effective technology was sorely lacking. Modern tools for exploring those realms had not been invented.

During World War I electro-therapy began to be utilized to hasten recovery of peripheral nerve injuries with some success. Nothing new developed in the field then for the years between the wars. During the later stages of World War II, and soon after, emphasis on the field of physical therapy and rehabilitation slowly gained in professional stature, though reliance was placed primarily on patient-initiated performance and exercise, and little on external light, sound, physical manipulation, or electrical physical therapy devices. Later diathermy and ultrasound were introduced.

Local electrical analgesia as a phenomenon then lay dormant until its republication by Wall and Sweet in 1967 under the impetus of investigations originally initiated to study the effects of 'gating' peripheral input. Melzack and Wall released their famous pain gate theory forming the conceptual basis of Transcutaneous Electrical Neuro-Stimulation. Kane and Taub reported temporarily abolishing chronic pain by electrically stimulating peripheral nerves via electrodes on the surface of the skin; the technique soon became known as 'Transcutaneous Electrical Nerve Stimulation (TENS)' (Wall and Sweet 1967).

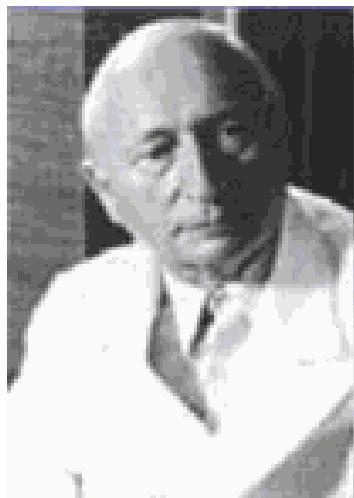
President Richard Nixon re-established relations with mainland China in the decade of the seventies, and the ancient art of acupuncture was introduced on a broad scale to the West. But in the early fifties, before the Nixon era cultural infusion, Dr. Rhinehold Voll had already developed

Electro-Acupuncture according to Voll (EAV) in Germany. Dr. Voll and his colleagues were already established as vanguards for developing scientifically based electro-therapy and electro-diagnosis well before acupuncture became popularized in America.

The application of electrical micro-currents to inserted acupuncture needles was soon adopted as a standard practice by many therapists in everyday practice, but the occidental mindset of western scientists was not just satisfied with observing the clinical outcomes of acupuncture therapy, but probed possible mechanisms of action, seeking to understand how acupuncture actually functioned. As East met West, new neuro-endocrinological and neuro-somatic models were developed. Some classical models were scrapped or modified to fit a still evolving scientific paradigm for comprehending cellular communications within the living body.

In order to acquire a true appreciation of modern BEST™ technology and its current application to therapy, the important contributions of several modern pioneers of the neuro-electrophysiological concepts are explained for the reader below.

Dr Reinhold Voll



In the early fifties, Reinhold Voll, a German medical doctor, developed an electronic testing device for finding acupuncture points. He was successful in finding acupuncture points and demonstrating that these points, known to Chinese acupuncturists for millennia, had a different resistance (impedance) to a tiny electrical current passing through the body, than did the adjacent tissues. Whereas acupuncture points displayed an impedance of about 50,000 ohms. Normal tissue displayed an impedance of 250,000 to 300,000 ohms. Many other researchers have also verified that electrical conductance at the acupuncture points is significantly greater than the surrounding tissue. Voll then began a lifelong search to identify correlations between disease states and changes in the electrical impedance of the various acupuncture points. He reasoned that if he was able to identify electrical changes in certain acupuncture points associated with certain diseases, then he

might be able to diagnose diseases more easily, or earlier. Earlier intervention was likely to be more effective. Voll was successful in identifying many acupuncture points related to specific conditions and published a great deal of information about using acupuncture points diagnostically.

Voll pioneered electro-dermal diagnosis. Before Voll's work, these ancient points had been used mainly for therapy. He found, for example, that patients with cancer in a specific organ had abnormal readings on the acupuncture points referred to as the respective organ points. Changes also occurred in the electrical impedance of specific acupuncture points associated with the inflamed musculoskeletal structures. Voll was very astute in observing and delineating the concept of biologically closed circuits and modulation of conductance/impedance of the circuits of his clinical interest. This opened the door for future researchers such as Nordenstrom and Becker to expand his concepts.

Voll discovered that certain acupuncture points showed abnormal readings when subjects were reacting in an inflammatory mode. A classic inflammatory condition he observed extensively was allergy. He made several serendipitous discoveries related to "allergy" testing. He noted some unusual readings on certain acupuncture points when a patient had a bottle of medicine in his

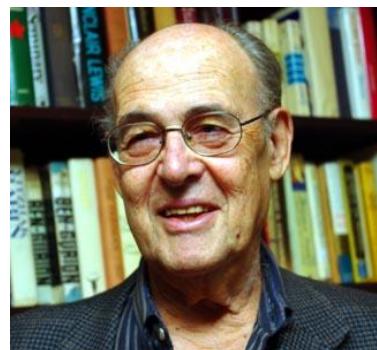
pocket. He could remove the bottle and consistently get different readings when the bottle was in his pocket compared to when it was not. At first he was baffled as to how a closed bottle of medicine outside the body could affect the acupuncture readings. It was even more baffling when he discovered that the glass bottle of medicine could change the readings when it was in contact anywhere along the closed electric circuit involved with the testing procedure. Placing a bottle of medication directly on the skin associated with an acupuncture point or meridian had a profound effect on his impedance measurements.

Voll and his colleagues then began work to identify the nature of these strange phenomena. They inserted a metal plate into the circuit and demonstrated that many substances that prelude changes in acupuncture point readings when ingested could produce the same changes when placed on the plate (even in closed glass bottles). They assumed that there must be some kind of electro-magnetic energy being emitted from the substances, and that these energy fields somehow traveled along the electric circuit to the body (perhaps like the energy waves representing a person's voice travels along the electric circuitry of a telephone line). From these findings, Voll developed an extensive system of electro-dermal diagnostic and therapeutic instrumentation that is still in use by electro-acupuncturist around the world.

Patrick David Wall and Ronald Melzack



Patrick David Wall



Ronald Melzack

In 1962, Ronald Melzack, a Canadian psychologist, and Patrick David Wall, a British physician, presented the idea that the perception of physical pain is not a direct result of activation of nociceptors (the ending of sensory afferent nerve fibers) but instead is modulated by interaction between different neurons both pain-transmitting and non-pain-transmitting motor, proprioceptive etc. Activation of these nerves can block transmission of pain signals from afferent nerves, competitively inhibiting them from transmission.

The Gate theory of pain postulates that in each dorsal horn of the spinal cord there is a gate-like mechanism which inhibits or facilitates the flow of afferent pain impulses into the spinal cord before it evokes pain perception and response. Opening or closing of the 'gate' is dependent on the relative activity in the large diameter myelinated (A-beta) and small diameter fibres (A-d and C). Activity in the large diameter myelinated fibres tends to close the 'gate,' and activity in the small diameter fibres tends to open it. TENS unit operation is consistent with this theory. Entry into the central nervous system (CNS) can be viewed as a gate which is opened by afferent pain impulses and closed by TENS low intensity stimulation.

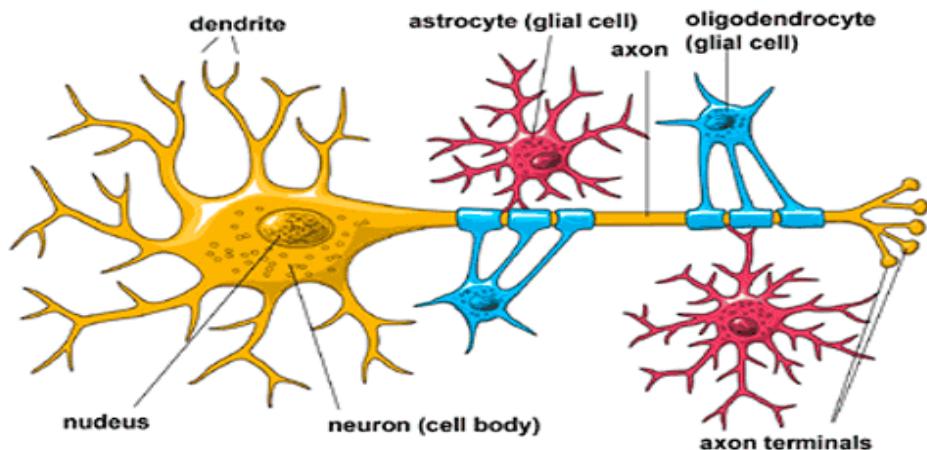
Dr. Robert O. Becker



Dr. Becker described what he believed to be two separate nervous systems, one of which is responsible for the generation of the channels or meridians of energy flow of the vital energies. In the developing nervous system (NS) outside the central nervous system (CNS), perineural cells, cells which support the nerves in many ways, embryologically form first. Neurons develop into tracts that grow within the pathway formed by the perineural cells. Perineural cells consisting of Schwann cells and Glial cells, which outnumber the nerve cells, wrap themselves around the nerve axons. Schwann cells consist of layers of “myelin”, a type of lipid that acts like an insulator on an electric wire. One result of this arrangement is more rapid nerve transmission of impulses.

Neuron signaling is digital in nature, with action potentials are propagated for “on” or non-propagation - “off”. This is because nerve conduction is facilitated by sudden changes in the permeability of cell membranes, by voltage gated channels that open and close. Net charge is based upon the differences of positive and negative charges within the cell in respect to outside the cell. As the character of the charged ions change, the net charge changes. This is termed “transmembrane ion flux.” The net charge before depolarization is restored by actively pumping the ions back out after the ionic inversion to restore the resting-state charge, before the event. Switching “on” is depolarization and switching back to “off” is repolarization, “off” also being the normal charge of the resting state of the neuron. The event/unit time of depolarization/repolarization is called an “action potential.” The generation and propagation of action potential are “all or none” events, hence communication by neurons in the nervous system is digital in nature. The action potential moves up the axon of a neuron like a tsunami wave through water.

Becker elucidated a second energetic and informational network which he termed the “Perineural Nervous System”, consisting of connective tissue, Schwann cells, and Glial (astrocytes and oligodendrocytes) surrounding axons and nerve fibers. The perineural system is analog in nature and generates slow moving bi-directional waves of direct current that flows throughout all tissues of the body, communicating integral and regulatory information on the cellular level.



Typical neuron cell body with supporting *glial* cell structures within a fiber, ganglion, or the CNS. The glial cells form the second communication system Becker termed the “*Perineural Nervous System*”.



Becker confirmed Nobel Laureate Albert Saint Gorgyi's hypothesis of solid state communication within the living intracellular matrix of connective substances that cements, not just the perineural nervous system cells into communication tracts, but all cells into their respective tissues.

The clinical implications of Becker's discoveries were successfully applied for the regeneration of damaged or missing tissues/appendages, healing of wounds, and regulation of the abnormal nervous system. The Perineural System senses and communicates injury by emitting a positively charged current, which Becker termed the "current of injury."

The positively charged injury environment with respect to normal surrounding tissues creates an environment for repair and controls the healing process. Negatively charged substances such as proteins and nutrients are attracted to the area for incorporation in the healing process.

Dr. Becker found the Acupuncture Points to be stable and to produce minute direct currents. The Acupuncture Points then are DC booster amplifiers spaced along the Acupuncture Meridians. Thus, the direct currents of injury are carried to the brain, interpreted as pain, and stimulate the output signals for modulating the healing process. This creates a closed-loop negative feedback system. Tissue fibroblasts secrete collagen (scarring) and sensitive cells de-differentiate and proliferate to repair the injury. A primary regulator in the healing process is the secretion of substances by the brain, spinal cord, gut, and peripheral nerve fibers, termed "neuro-peptides" (NP). Many NPs are regulatory in nature and modulate long-term homeostatic mechanisms. Becker described direct nerve to epithelial cell attachments in the skin called neuro-epidermal junctions (NEJs). These junctions are crucial for any real complete healing to occur. Both these components, perineural cells and NEJs, make up the physical structures which guide the healing properties inherent in the genetic material within the nucleus of every living cell of the body. Becker believed these junctions are connected to, and are related to, the acupuncture meridian system. It is these NEJs that create the minute (+) direct current of injury at the site of trauma and thus informs the CNS where the injury is located through the perineural cells, by amplifying and boosting the signal along the meridians.

Becker's work has been foundational in the West for the field of regenerative medicine. His work served as a basis for present stem cell research and their clinical applications. In addition, his work in elucidating the nature of the perineural nervous system provided scientific evidence for the existence of acupuncture points and meridians and explained their functioning in the western mindset.

Erwin Neher and Bert Sakmann



Erwin Neher



Bert Sakmann

At the same time Becker began conducting his clinical research into wound healing and tissue regeneration, Erwin Neher and Bert Sakmann developed the “patch clamp method” to prove the existence of ion channels incorporated within the outer membrane that enclose the cell.

Neher and Sakmann were awarded the Nobel Prize in Medicine for their efforts. With this method, the ionic current is measured on a tiny membrane patch to which a predetermined voltage clamp is applied. Working within a microscopic world of minute subcellular structures required extreme sensitivity for measuring in angstroms, microns, and pico-amps, within microseconds observation intervals, and required exceptional agility for micro-manipulation of the patch. This patch is only a few square micrometers in size and contains a single ion channel. When the current is measured, abrupt, short-term jolts can be observed: the channel opens, ions flow through it, and electrical charges transfer from one side of the membrane to the other. Then the channel closes again. Currents of a few pico-Ampere can be measured within as little as one millisecond.

In 1976 Neher and Sakmann succeeded in measuring the ionic current of single channels in the cell membrane of a muscle fiber. The patch clamp measurement apparatus used to provide evidence of the existence of ion channels was developed at the Max Planck Institute for Biophysical Chemistry in Göttingen and can today be viewed in the German Museum in Bonn. This experimental setup led to molecular electrophysiology as a recognized science.

Neher and Sakmann’s work has been foundational in understanding diseases termed channelopathies, the failure or defective function of ion channels within cell membranes. Structural proteins that comprise the walls of ion channels can be defective due to genetic damage. Ion channels are also involved in myocardial arrhythmia, diabetes, high blood pressure, incontinence, multiple sclerosis, angina pectoris and epileptic seizures. Ion channels that rely on voltage to open and close (termed “voltage gated ion channels,” VG) fail to function, simply because there is not enough potential difference in charge between outside and inside of the membrane (energy) to operate. By charging the inside of the cell membrane, which stores charge like an electronic capacitor, electro stimulation devices restore the energy necessary for voltage-gated channels to function correctly. A critical function associated with VG ion channels is the regulation of blood perfusion. Neher and Sakmann’s contribution to understanding cell membrane electrophysiology through the “patch clamp” has been invaluable to the fields of medicine, cell biology, pharmacology, and agriculture, and are used extensively in research laboratories throughout the world.

Dr. Peter Fraser



Physicist Peter Fraser, regarded as the world's expert on the human body field, wrote an article in which he expands on Becker's finding as to the analog nature of perineural communication and its higher level regulation of the nervous system by using field theory as a conceptual approach.

"What is so difficult to explain about the nervous system is that it is discontinuous electrically, so clearly an electrical explanation cannot seriously be considered as an explanation. The nervous system is also discontinuous chemically, since there are synapses placed at irregular intervals in the nervous system. So, if it's not electrochemical in essence, then why is the electrochemical system even part of the nervous system's makeup? Could it be that it is there to provide the right energetic environment to make the nervous system work as a field mechanism? That's my thinking at this time. And what's more, it's an energy saving device so that it only works at the instant it's needed, when the nervous system needs a sudden and immediate charge, and it works in the places where it is needed by the nervous system. So for that the electrical system works, but not for an overall explanation of the nervous system.

It is interesting to note, too, that the electrical aspect of the nervous system works completely outside of the actual nervous tissue itself. This is a real problem! The mechanism of charge and depolarization works outside of the nerve cell".

SEVEN PRINCIPLES OF THE HUMAN BODY FIELD

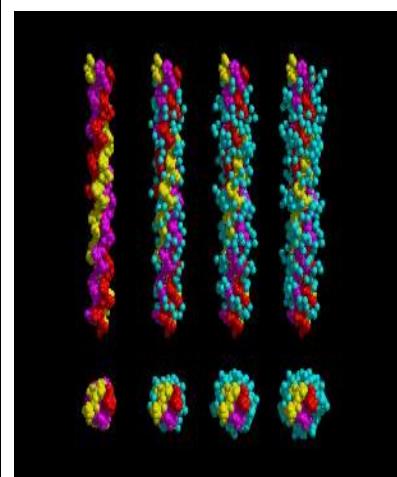
Fraser discusses the physics of resonating cavities on a macro-level arranged in the human body and micro-level as arranged in cells and tissues. He discusses communication as "pure spatial information presented in terms of structures." Fraser defines "energetic pathology" as disease states that arise when the body is forced to use less than optimal pathways of energy and communication transmission to get its work done; pathways form organ to organ and cell to cell, nerve to nerve, even system to system. The breakdown starts in the body-field and distorts the flow of energy and communications. This is in contrast to more conventional biochemical views of pathology. This powerful article goes far in understanding the existence and function of the human body field, and further aids in the concepts of vegetative tissue dysfunctions and subconscious (non-nervous system), cellular communications such as acupuncture phenomenon.

Mae Won Ho



Further reinforcing Fraser's concept of "pure spatial information presented in terms of structures," Dr. Mae Won Ho has written extensively on the structure of water in living systems.

In her book *The Rainbow and the Worm* and several of her published papers, Dr. Ho explains how water bound on surfaces of proteins and membranes conducts positive electricity and could enable cells and tissues to intercommunicate rapidly and efficiently. But for transmission of positive electricity to occur, water must be structured in a sufficiently ordered form and space for a proton jump to occur from one water molecule to the next.



Hydration model of a triple helix collagen molecule over time

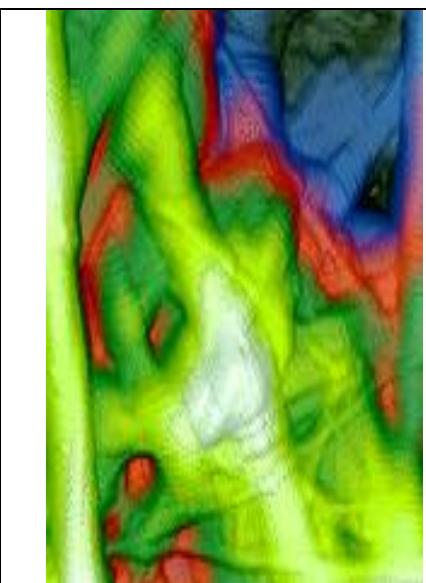
This serial graphic at the left is a demonstration of water hydrating Collagen over time. Positive electricity by jump proton conduction flows through collagen-bound water.

Damaged collagen retains memory of injury through the distorted crystalline structure of the water. Injured tissue inhibits proper flow. Micro-current therapy restores normal conductivity by using charge flowing through the liquid crystalline water bound to bring collagen chains back into alignment.

Diagram-Rutgers University

Protein and membrane surfaces in a living organism impose that kind of order on water. The spatial arrangements allow for a proton from one water molecule bound to a structural protein to jump to the next, and so on, allowing for the conduction of positive electricity. Jump conduction is faster than ordinary electricity passing through a metal wire, which involves electrons actually moving, and much, much faster than conduction by charged ions diffusing through water as displayed in neuronal action potentials.

Dr. Ho proposed that the acupuncture system and the DC body field of Becker (Perineural) and Fraser Human Body Field is actually a continuum of liquid crystalline collagen fibers that make up the bulk of the connective tissues (again Saint Gorgyi cellular solid state communications idea). Bound water layers (a pure spatial informational relationship presented in structure) on the collagen fibers provide proton conduction pathways for rapid intercommunication throughout the body, enabling the organism to function as a coherent whole. Her liquid crystalline continuum mediated hyper-reactivity to allergens (a manifestation of Fraser's energetic pathology) and the body's responsiveness to different forms of subtle energy medicine. It constitutes a "body consciousness" (analog) working in tandem with the "brain consciousness" (digital) of the nervous system.



Proof of the Crystalline Structure of Collagen

Micro pictograph of actual collagen molecules under polarized light displaying the hallmark of crystalline structures known as "bi-refringence." As the plane of polarized light illuminating the microscopic dark field is shifted, the molecules refract different colors. Refraction characteristics under polarized light also change with the percentage of hydration of the collagen molecule.

<http://micro.magnet.fsu.edu>

The phenomenon of bi-refringence, the changing rainbow of colored light emitted during exposure of a substance to polarized light, is the classic hallmark of crystalline structure. Collagen consists in nature of a three-stranded triple helix structure. Collagen contains the amino acid “Proline.” Proline is incorporated in the structural backbone of collagen, because its hydrogen bonding characteristics are responsible for the helical conformation, and also for binding large amount of water to its exposed hydroxyl group jutting out from the surface of the molecule. In fact, collagen is saturated on its surface with water. It is this bound water that forms the liquid crystal conduction matrix. Ho refers to the bi-refringence of saturated collagen as evidence of water bound to the surface of collagen acting as a liquid crystal or semiconductor for proton conduction. It is also known that meridians conduct photons of light conduction.

A. N. Revenko and A. Karasev



A.N. Revenko



A. Karasev

The Western approach to neuro-therapy for pain abatement focused on the nervous system. Information is digitally originated by electrochemical impulses and propagated along the axon of neurons to synapses and higher centers of the brain. While Russian scientists accepted this approach, they did not limit their search for more effective therapies exclusively to the nervous system. Revenko, Karasev, and other Russian Scientists explored another form of cells utilized to communicate with other cells of the body, communication possessing an analog form of signaling. They developed the concept that traumatized tissue retains a “memory of injury” in the form of blocked analog signaling to the brain, and that the injury memory contributed to vegetative (chronic non-healing) tissue dysfunction of traumatized or pathologically affected tissue. When one tissue or organ is depleted of electrons then the metabolic function of the tissue degenerates, and the body makes adjustments by pulling energy (voltage, electrons) from other tissues in a balancing act to maintain the highest level of capacitance (i.e. maximum reduction/oxidation potential, charge) possible for energy resources available. Organs are paired so that deficient organs will borrow energy (charge, electrons) from their partner to remedy the deficiency. This process continues until the donating organ degenerates, which in turn will borrow from wherever possible. The body continues to compensate for electron deficiency and signaling patterns, exacerbating in a downward spiral to a terminal event.

Electro-stimulation devices termed SCENAR (Self Controlled Energetic Neuro-Adaptive Regulation) were developed in Russia in the mid-seventies by A. Karasev, based at Sochi University, and extensively refined by Professor A.N. Revenko (neurologist) and Ya.Z. Grinberg (electrical engineer) and many physicians and scientists based in Taganrog, Russia. They were among the first researchers to achieve repeatable therapeutic results using electrical signals to stimulate the immune system. Their devices were created for use by the Russian military and space programs with the advantages of being inexpensive, lightweight, space saving, and a practical substitute for pharmaceutical therapy. Theoretically, pharmacy supplies on board space vessels could be reduced, saving space and weight. In 1986 their first electro-stimulation device

passed technical and clinical trials and was cleared by the USSR Medical Council for use in hospitals and in homes. Devices carried by the Russian Military were used to effectively treat shock and as a substitute for morphine on the battlefield. It is known that SCENAR was probably developed at a much earlier date than officially stated. Before their release to the world, the technology remained a closely guarded state secret. After the reorganization of the USSR, the technology was declassified and released to the world for humanitarian relief as a gesture of good will and a furtherance of Perestroika.

Donald Shearn first demonstrated *biofeedback* using Operant conditioning of heart rate in 1962. Neal Miller later used this procedure and hypothesized that any measurable physiological behavior within the human body would respond in some way to voluntary control. Miller, in cooperation with his graduate assistant De Cara, discovered reinforcement by electrically stimulating the pleasure centers of a paralyzed rat's brain induced changes in various physiological values.

The traditional meaning of the term *biofeedback* then, whether measuring skin impedance, blood pressure, body temperature, heart rate, muscle tone etc., is the use of the *conscience* mind to control *unconscious* functions (autonomic nervous system). The assumed model for biofeedback was by behavioral conditioning (learning), although this model has always been conjectural and never fully confirmed.

As biofeedback therapy developed in the West and struggled for professional acceptance among medical and mental health practitioners, a parallel Russian model for learned biofeedback behavior was developed, scientifically confirmed, and successfully implemented into their healthcare system. A second form of biofeedback that did not require the mediation of the conscious mind was also successfully developed. This second form of biofeedback was associated with the conditioning principles of behaviorism and had no requirement for volition or learning. This form of biofeedback was labeled reflex biofeedback in contrast to conscience learning biofeedback. In reflex biofeedback, directing micro-current stimulations of the body by way of reflexive pathways in the skin evokes informational responses to the brain. The skin and nervous system are both derived embryologically from the ectoderm layer of the developing blastocyst. Hence, the presence of Becker's nerve to epithelial cell attachments in the skin called neuro-epidermal junctions (NEJs). The Russians developed a biofeedback device they termed SCENAR for applying to the skin. Like Voll's impedance assessment concepts, the electrical properties of points and regions on the skin provided points of assessment for the nervous system and the internal organs that were innervated by them; the same points and regions were also used for therapeutic intervention by inputting stimulation by their device.

The cybernetic loop signaling based upon impedance as a manifestation of unconscious reflex biofeedback was utilized.

Cybernetics is defined as the science of communication and control processes within systems. Control is based on communication, both within the system and with the external environment, and influences the actions of the system to bring it into some desired future state or to maintain homeostasis. Cybernetics includes the concepts of auto-regulation and feedback as well as the transmission and self-correction of information, and can be applied not only to machines like computers but also to living organisms, including humans, and to complex organizations and societies.

In this case the living human organism and a machine (i.e. electrical impedance driven device) form an energetic and informational loop to self-correct aberrant tissue, organ, or system function.

The signaling developed, displayed a high voltage (200-300 volts) extremely short duration (micro seconds 10-6) damped, sinusoidal waveform that corresponded to the digital type signaling in the small unmyelinated nerve fibers. Habituation and accommodation, a common phenomenon with nerve stimulation was avoided by the constantly changing signaling, driven by the cybernetic loop. In essence the body through the medium of the skin actually directed the device as to what type of energy and information that it needed.

The analog, perineural system, body field was also affected.

Neuro-adaptation is an unconscious biofeedback loop involving a specific tissue organ, or system and the brain cortex. When an abnormal condition occurs, and could include pathology or trauma, the perineural system, or body field senses the disturbance and sends analog signals (possibly by incoherence of water bound collagen or disturbances in conductance of meridians) to higher centers in the cortex. Concurrently nociceptors (sensory nerve endings of c-fibers) and c-fibers may sense a direct disruption due to damage in their immediate area or sense an indirect disruption of the body field and relay digital signaling through the spinal thalamic tract to the cortex. The cortex then sets up an area to deal with the abnormality comparing the abnormality with a template of normal. The cortical center then directs the hypothalamus to reset the affected area by physiological intervention, including the release of modulating neuro-peptides. After a restoration of normal, the cortical center directing the adaptive restoration dissolves. When the neuro-adaptive loop breaks down or fails to complete a successful adaptation, the biofeedback device is inserted into the loop to provide energy and information to complete the process of adaptation and restoration.

Tim Smith



Brooks Smith began teaching his son electronics when Tim was in the eighth grade. Together they built vacuum tube radios, a short wave radio, and a stereo set. By the time Tim was in the eleventh grade, he knew that he was going to be an electrical engineer. Following graduation from Southern Methodist University with his BSEE, Tim joined Texas Instruments designing integrated circuit chips. Over the next four years, Tim designed chips during work hours and attended night school to get his MSEE in 1969.

Tim Smith is a truly impressive electronic engineer. Between the ages of 24 and 27, Tim Smith managed the design team that developed the integrated circuit chips for the Poseidon and Minuteman Missiles. Tim Smith also designed the IC chips that landed the Apollo Astronauts on the Moon and brought them safely back home.

At age 29, design engineer Tim Smith invented the premier logic product line for Texas Instruments, known in the industry as Low Power Schottky. This one product line became the work horse of the computer and telecommunication industries, netting



Texas Instruments over 30 billion dollars in sales since its inception in 1971 and has been an integral component for nearly every major computer system, telecom system, and military system in the western world. For this invention, Mr. Smith received Texas Instruments' highest honor—the Patrick E. Haggerty Innovation Award. Systems utilizing Tim Smith's inventions can be found in all modern telecom systems, computers, the Space Shuttle, military fighters such as the F-14, F-15, the B1 and B2 bombers, and Boeing/Airbus airliners. Tim Smith's innovations touch the lives of billions of people around the world every day. Anyone who flies on a commercial airliner or uses a cell phone or computer has been touched by Tim Smith's work.

After building a legacy at Texas Instruments by further developing the Analog and CMOS businesses, Mr. Smith left TI to pursue other ventures. Searching for an endeavor worthy of his calling, and desiring to utilize the wealth of knowledge and experience gained in his engineering career, Tim Smith focused on the problem of human and animal pain, a truly universal problem in need of more effective solutions. Pain cuts across species, gender, race, age, and geography, leaving no one on the planet untouched. In 2009 chronic pain is estimated to cost the US economy \$150 billion per year.

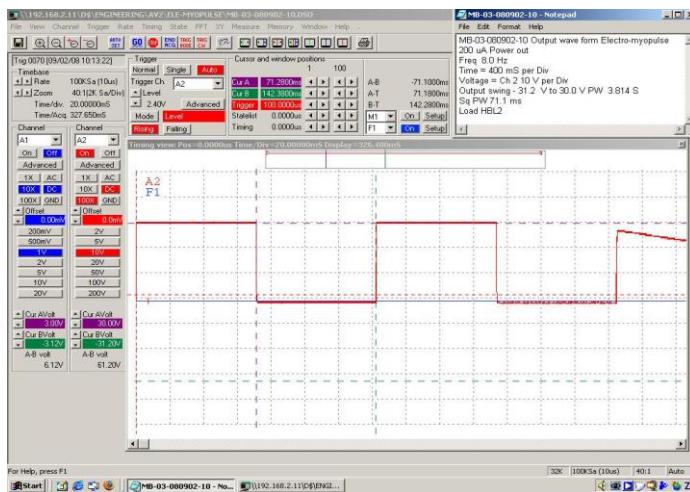
A better answer to pain would be one simple-to-use device, possessing greater therapeutic and cost effectiveness, and non-pharmaceutical in nature. By achieving these goals, Tim Smith realized he could again touch billions of lives on a scale similar to his earlier days at TI. In 2004 Tim Smith founded Avazzia, Inc. as a platform to develop high technology medical electronic therapeutic and diagnostic devices, especially emphasizing an electronic answer to the problem of pain!

The realization that the use of subtle energy with the correct signature can influence physiologic mechanisms for tissue regeneration, pain abatement, and immune modulation in living organisms became his new passion. Tim Smith has positioned Avazzia to become a worldwide leader in translating doctors' and medical scientists' diagnostic and therapeutic concepts into viable, reliable real life working technology. When asked about his vision, his response is that subtle energy can impact how medicine is practiced on a global scale. The future vision for Avazzia is where modern electronics meets modern medicine to provide practical, effective solutions now and for generations to come!

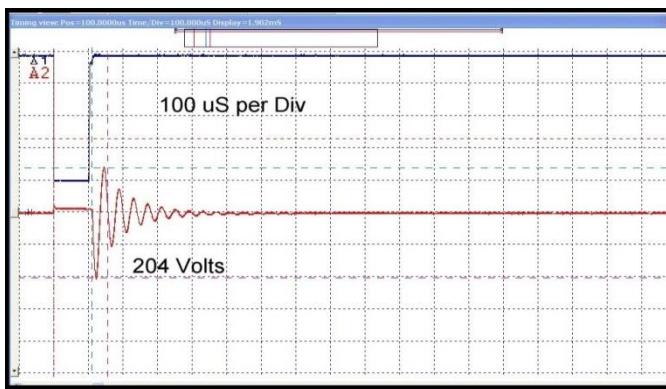
AVAZZIA TECHNOLOGY

Avazzia BEST™ devices are Microcurrent Biofeedback Electro Stimulation Technology devices. They are not just TENS devices.

Most conventional TENS technology works based on the “pain gate” theory. That is, they apply sufficient electrical charge to the “A” and “B” fibers of the nervous system to saturate them and thereby block the communication of pain to the brain. Often, when the stimulation is removed, the pain returns in a short period of time. An oscilloscope trace of a conventional TENS signal is shown below. Note the signals are monophasic-square wave in nature with voltage from 0 to 30 volts. Their duty cycle is approximately 50%.



Avazzia BEST™ (Biofeedback Electro Stimulation Technology) is based on a completely different operating theory. BEST™ devices generate electrical impulses that are physiologically similar to neurological impulses observed in the “C” nerve fibers embedded in tissues and consist of 85% of all nerves found in the body and to “fast” pain blocking A fibers.



A BEST™ device communicates with the neuro-endocrine system through direct touch to the skin, sending a signal through the epidermis and dermis into underlying fascia planes and is transmitted through connective tissue to the C and A nerve fibers.

BEST™ devices actually seek decreased impedance on skin by “sticking” (dramatic increase in friction) to acupuncture or electron deficient sump points when gliding the instrument over the skin. The area may comprise injured or diseased tissue or may be associated with an organ or corresponding structure with that anatomical segment. Electrons supplied by a BEST™ unit placed at the correct location on the skin are channeled by the integrated system of connective tissue within the body to the lowest electron deficiency. The normal energetic equilibrium between various tissues and organs is restored, and the redox potential of the body is recharged.

Published medical research has identified the electrical signal characteristics that affect the thin “C” fibers of the nervous system and result in the stimulation of nitric oxide, hormones, endorphins, and neuropeptides. Other publications indicate the signal characteristics and treatment locations that balance the sympathetic and parasympathetic nervous systems. (Sympathetic and parasympathetic divisions typically function in opposition to each other. But this opposition is better understood as complementary in nature rather than antagonistic. For an analogy, one may think of the sympathetic division as the accelerator and the parasympathetic division as the brake.) Appendix A presents references with regard to the effect of electrical stimulation on physiology and wound healing.

Avazzia devices utilizing BEST™ (Biofeedback Electro Stimulation Technology) represent an entirely new generation of TENS technology that employs electrical signals targeted towards releasing of nitric oxide, endorphins, and neuropeptides into the blood stream.

- Nitric oxide causes vascular dilatation and thereby increases blood circulation.
- Endorphins are the body’s natural pain management chemicals.
- Neuropeptides are the body’s regulatory elements that promote accelerated healing.

Avazzia BEST™ electrical signal characteristics that encourage the above effects are:

- Short duration pulses of high voltage amplitude and very low duty cycle;
- Average currents in the microcurrent range; and,
- Damped bi-phasic, sinusoidal waveforms.

The process is further enhanced by signals that change and adapt as the electrical properties of the tissue being treated change (hence biofeedback).

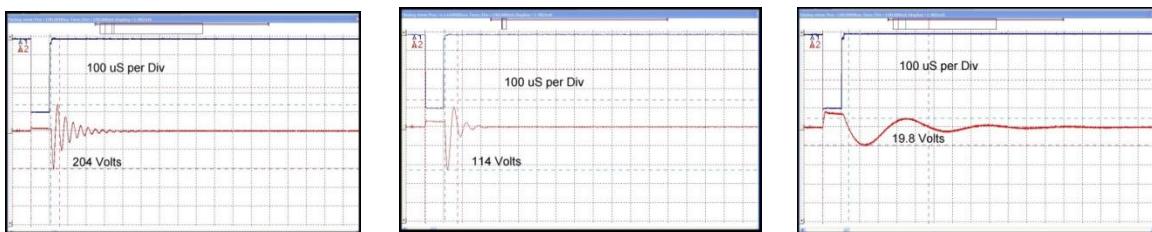
These electrical signal properties are attained by using patent-pending algorithms that produce specific patterns of output pulses for specific applications. Avazzia technology quickly provides relief of chronic and other pains. The pain relief is long lasting (up to 12 hours).

BEST™ technology generates waveforms such that there is no habituation or accommodation, i.e. tolerance, developed by the body.

BEST™ Technology vs. Conventional TENS

TENS was developed for the control of chronic and post-operative pain by saturating subcutaneous nerve receptors with low-intensity, electrical stimulation in order to effect a specific dermatome or anatomical segment where the main source of pain resides. TENS delivers constant voltage with fluctuating current and resistance/impedance whereas BEST™ delivers a driving signal based upon the change in micro-current and impedance over the active pulse interval. Unlike TENS, which relies on constant and externally generated signaling principles, BEST™ is based upon the development of a cybernetic feedback loop.

BEST™ signaling is an electrical control system, external to the body, which interfaces directly with the skin and transcutaneously communicates with the internal peripheral nervous system for the purpose of therapeutic intervention. This is possible because of the development of modern high-speed microprocessors, which are able to establish a “cybernetic loop” between electronic instrument and living body. The body’s response can be measured with respect to a signal sent out from the instrument to initiate the loop. When a signal is emitted and penetrates deep into the tissue, the impedance of the tissue (analogous to resistance in DC circuits but dynamic in nature) modulates the next waveform. The degree of modulation is based upon the changes of impedance of skin as signals are applied. This sets up a constantly changing interactive bio-loop possessing non-repeating signals. Eventually the change in impedance diminishes in significance until a plateau occurs.



A comparison of conventional TENS and Avazzia BEST™ follows:

Conventional TENS	BEST™
Signals in the frequency range of 1Hz to 100Hz, low intensity pulses, activation of Type I and A- β afferent fibers based upon Gate control theory mechanism and signal blocking or diversion	Signals in the frequency range of 1Hz to 500Hz, high intensity pulses, direct effect on secretory C fibers, also significant CNS effects via C afferents to spinal ascending and opioid mediated descending inhibitory pathways.
Mono-phasic or asymmetrical biphasic waveform	Damped asymmetrical biphasic sinusoidal waveform
Low intensity activates large muscle (type I) and large skin A- β nerves for Gate effect.	High intensity, short duration pulses, induces neuropeptide release, initiates long-term cascading effects and up-regulation of NP, endorphin, serotonin, and encephalin synthesis.
Segmental effects based on Gate Theory: large diameter fibers inhibit pain from small fibers.	Non-segmental and segmental effects: neuropeptide cascade initiated by small C fibers act generally as well as locally: in spine, brainstem, and CNS.
Analgesia starts within a few moments of stimulation and disappears within seconds of switching the machine off. TENS must be used for long periods of time for sustained relief.	Analgesia starts within moments and lasts up to twelve hours with both local and systemic pain relief.
High intensity of most TENS devices can cause burning of skin.	BEST™ micro-ampere output current reduces chance of burns or irritation.
Pads are placed near the site of pain as large diameter fibers are widely distributed.	No Pads are necessary as the electrode on the unit both transmits and receives. The unit can be placed on acupuncture points or over subcutaneous large diameter nerves as well as directly on areas of interest or pain. Electrodes for point source delivery are available. For Convenience, pads and conductive garments are attachable.
Tolerance (accommodation and habituation phenomenon) develops over time.	Because of dynamic waveform and cybernetic feedback, habituation or accommodation is avoided.
Prolonged duty cycle, long durations of “on” operation compared to “off” condition	Short duty cycle with BEST™. Typical unit is “off” over 99% of the time and emits burst signals less than 1% of the treatment time.
TENS is constant voltage signal with variable changes in current and resistance/ impedance over the pulse interval.	BEST™ delivers signals with voltages and currents varying as the impedance of the skin is changed as result to prior stimulation pulses.
External control with no bio-feedback modulation of the output signal. TENS signaling is constant although some models have a fixed external program that varies signaling to resist accommodation or habituation.	Cybernetic loop whereby BEST™ and the patient’s neurological system form a mutually interacting communication and control system via automatic biofeedback and impedance signaling of affected tissues.

One of the main factors that makes Avazzia stand out from its competition is its technology: state-of-the-art microcurrent Biofeedback Electro Stimulation Technology. It is most illustrative to segregate TENS technology according to four categories of technology: first generation TENS, second generation TENS, third generation or microcurrent TENS and fourth generation Biofeedback Electro Stimulation Technology.

The earliest TENS devices, developed in the 1930s, have mono-phasic square-wave signals and worked at 10 to 500 mA (milli-Ampere). This technology has serious drawbacks: one is habituation (it only treats pain for several weeks, after which time the body accommodates or habituates to the stimulation and no longer blocks the pain). The other serious drawback of this technology is its short period of pain relief (less than one hour). It is an obsolete technology but is still available today. We call this group first generation TENS.

The second generation TENS group, developed in the 1970s, has an asymmetrical bi-phasic square wave output. Bi-phasic means the signal goes plus and minus relative to a reference voltage. Asymmetrical means the plus and minus signals are not equal in time of application and/or voltage. The improvement over the earliest TENS is that habituation is reduced. But the pain relief is still brief (< 1 hour). This is an obsolete technology but is still available today.

Third generation, or interferential TENS technology, was subsequently developed with asymmetrical, bi-phasic, and irregular shaped, microcurrent wave outputs. These wave forms result in partial opioid mode and partial pain gate mode. Opioid mode means that the electrical stimulation results in the production by the body of endogenous opioid peptides which mitigate pain. Pain gate mode means the A and B nerve fibers are stimulated to inhibit an individual's perception of pain. This technology was an improvement in that the pain relief period was increased and habituation was reduced. This technology is not obsolete, with devices available today.

With fourth generation TENS, subsequently it was observed that:

- Pulsed high voltage (>250 volts), low duty cycle (<10%), micro current signals were more effective in stimulating the thin c-fibers of the nervous system than square wave signals.
- An asymmetrical wave form reduces habituation.
- The use of electrical feedback to adjust the waveform as the electrical properties of the tissue being treated changes further reduces habituation and allows the technology to measure the progress of the treatment and provide information to the medical practitioner.
- Sine wave signals more closely approximate the natural signals in the nervous system.

The following table summarizes the characteristics of the four TENS technologies:

Characteristics	TENS			
	First Generation	Second Generation	Third Generation (interferential)	Interactive Biofeedback (Avazzia's product)
• Wave Form	Square Wave	Square Wave	Square Wave with Spikes	Damped Sinusoidal
• Biphasic or Monophasic	Monophasic	Biphasic	Biphasic	Biphasic
• Treatment Current	Milliampere	Milliampere	Microampere	Microampere
• Voltage	Low voltage	Low voltage	Pulsed High Voltage	Pulsed High Voltage
• Interactive Biofeedback	No	No	No	Yes
Habituation	Serious problem	Reduced	Greatly Reduced	Eliminated
Principle Treatment Effects	Gate Mode	Gate Mode	Pain Gate + Opioid Mode	Pain Gate + Opioid Mode
Length of Pain Relief (Hours)	< 1 Hour	< 1 Hour	1 to 2 Hours	6 to 8 Hours
Diagnostic Indication	No	No	No	Yes

AVAZZIA MODES

The Best-Pro 1TM and Best-RSITM devices are US FDA cleared for:

“symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-surgical and post-traumatic pain”.

The Pro-Sport IITM device is FDA classification 882.5050 Neurology Biofeedback device.

- a) Identification. A biofeedback device is an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological parameters (e.g., brain alpha wave activity, muscle activity, skin temperature, etc.) so that the patient can control voluntarily these physiological parameters.
- b) Classification. Class II (special controls). The device is exempt from the pre-market notification procedures in subpart E of part 807 of this chapter when it is a prescription battery powered device that is indicated for relaxation training and muscle reeducation and prescription use, subject to § 882.9.

The chart below identifies the modes contained in the Best-Pro 1TM, Best-RSITM, and Pro-Sport II IITM devices.

MODE	Best-PRO 1 TM	Best-RSI TM	Pro-Sport II II TM
Relax/Assess	X	X	X
Blue Relax			X
Stimulate	X		X
Deep Stimulation	X	X	X
Blue Stimulation			X
Massage			X
RSI		X	X
Acute	X	X	X
Acute Trauma			X
VASO			X
AVA			X
783 Harmonics			X
Alpha 7-12			X
Beta 12 – 31.2			X
Delta .5 – 4.0			X
Gama 37 – 43			X
Theta 3 – 8			X
Tone 1			X
Tone Plus			X
Tone Plus			X

Tone Advanced	X
Tone Intense	X
PG 2500	X
HGH	X

Relax/Assess

The Relax/Assess mode is a dual purpose mode. The same mode is used in treatment and used by health care practitioners to determine the Initial Reaction at the positions of contact on the patient. For pain relief treatment, it is used as a Relax mode. The Best-PRO 1™ and Best-RSI™ devices signal treatment process completion with a ring tone as well as a visual display.

In the Pro-Sport II™ device, one may select Biofeedback in the Relax/Assess mode to observe the device power setting, the Initial Reaction, the time of treatment, the Ongoing Reaction, the coefficients of form, Dose, Zero and Speed of reaction in a two row display. This is particularly useful to practitioners in assessing where to treat and to observe the treatment progress.

Blue Relax

The Blue Relax mode is available only in the Pro-Sport II™. For pain relief treatment, it is used as a Relax mode. One may select Biofeedback to observe the device power setting, the initial reaction, the time of treatment, the ongoing reaction, the coefficients of form, Dose, Zero, and speed of reaction in a two-row display. This is particularly useful to practitioners in assessing where to treat and to observe the treatment progress.

Stimulation, Deep Stimulation, and Blue Stimulation

Stimulation, Deep Stimulation, and Blue Stimulation modes are for microcurrent stimulation and pain relief. The frequency sets of Blue Stimulation are unique in the industry to Avazzia.

Massage

Massage mode is for biofeedback application to acute pain. It is a signal pattern unique to Avazzia technology. In this mode the user may select various modulation settings.

RSI

The RSI mode is Avazzia's strongest mode for chronic pain. It delivers the most energy per unit time of any similar device.

In the Pro-Sport II™ device, one may select Biofeedback to observe the power setting, the Initial Reaction, the time of treatment, the Ongoing Reaction, the coefficients of form, Dose, Zero, and speed of reaction in a two-row display. This is particularly useful to practitioners in assessing where to treat and to observe the treatment progress.

Acute and Acute Trauma

The Acute and Acute Trauma settings may be used for acute pain or for specialized applications as directed by a physician. The Acute Trauma mode is patent pending.

VASO

The VASO mode is Avazzia's strongest stimulation mode for pain management. The makeup of this mode is proprietary and the subject of an Avazzia patent. It consists of three phases. Each phase is made up of unique combinations of frequency and damping sets. Together the three phases provide a unique treatment.

AVA

The Pro-Sport III™ provides a AVAZZIA VARIABLE ADVANCED or AVA mode, which allows the practitioner to select individual treatment signal patterns based upon their professional preferences and experiences.

The control options are as follows:

Frequency, Hz	0.5 Hz to 1565 Hz
Power Modulation	7 modulations: 0.5, 1:1, 2:1, 3:1, 4:1, 5:1, and 6:1
Output damping	8 damping levels: 0, 1, 2, 3, 4, 5, 6, 7
Pulses per output	Up to 30
Control of time between pulses	001 to 80 multiples of 20 microseconds between each
Output power curves	The user may select one of 5 power curve ramp rates: Normal, Sensitive, Soft, Cosmetic, or Ultra Sensitive

In several modes, one may select Biofeedback to observe the power setting, the initial reaction, the time of treatment, the ongoing reaction, the coefficients of form, Dose, Zero, and speed of reaction in a two-row display. This is particularly useful to practitioners in assessing where to treat and to observe the treatment progress.

Safety Precautions

Read all safety instructions before operating. The device should only be used for the purpose of which it is intended.

Danger

The device can generate output pulses up to 650 Volts. To avoid skin irritations such as burns, do not use device for prolonged periods of time in a single location or while sleeping or otherwise unattended. Misuse could result in fire hazard.

Contra-Indications

This device should not be used on an individual who has a heart pacemaker or other electrically powered implant.

Warnings

- Safety of electro-stimulation devices for use during pregnancy or birth has not been established.
- Device is not effective for pain of central origin such as headaches.
- Device is a symptomatic treatment and as such may suppress the sensation of pain which would otherwise serve as a protective mechanism.
- The long-term effects of electrical stimulation are unknown.
- Stimulation should not be applied over the carotid sinus nerves (neck) region.
- Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur, and the contractions may be strong enough to close the airway or cause difficulty in breathing.
- Stimulation should not be applied trans-thoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- Do not allow any electrode placement that applies current flow transcerebrally (through the head).
- Stimulation should not be applied over, or in proximity to, cancerous lesions.
- Keep device out of reach of children. It is not a toy. It should not be used as a weapon.
- Device is not a life-saving device.
- Do not use in or near water.
- Do not operate while operating machinery or vehicles.
- Do not operate if unit has been dropped. Do not operate if case is damaged. Do not operate if unit does not function properly.
- Electronic monitoring equipment, such as ECG monitors and ECG alarms, may not operate properly when device stimulation is in use. Electro-pulses may interfere with pacemakers and/or other electronic and radiological equipment.

Additional Precautions

- Skin irritation and electrode burns have been reported at the site of electrode placement following long-term application. To reduce risk of skin burns, keep electrodes directly against skin during application.
- Effectiveness is highly dependent upon subject selection by a person qualified in the management of pain.
- Do not use device for undiagnosed pain syndromes until etiology is established.
- Caution should be used for persons with suspected or diagnosed heart problems.
- Caution should be used for persons with suspected or diagnosed epilepsy.
- Caution should be used in the presence of the following:
 - When there is a tendency to hemorrhage following acute trauma or fracture;
 - Following recent surgical procedures when muscle contraction may disrupt the healing process;
 - Over the menstruating or pregnant uterus; and
 - Over areas of the skin that lack normal sensation.
- Some persons may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, alternative electrode placement, or reduced output power.
- Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
- Results of use may be influenced by person's psychological state and use of drugs.

Adverse Reactions

Headaches, nausea, and light flu-like symptoms may accompany overuse. To avoid side effects, drink water before and after the therapy. Limit therapy to once or twice per day for 20 minutes for the first two to three days.

Sore muscles may accompany overuse if the device is applied such that muscle stimulation occurs. To avoid this, try to apply device such that muscle twitching does not occur and limit therapy to 15 to 20 minutes per session.

Terms and Definitions

Biofeedback — Bio means body, feedback means response or reaction. Avazzia's Biofeedback technology takes measurements with each output pulse, manipulates this data, and displays readings from the body including initial reaction readings and ongoing reaction readings as well as coefficients, ratios, and treatment progress readings. Every output pulse is modified as the body's tissue characteristics change such as resistance, capacitance, and rate of change. Indicators of the ongoing body's reaction are displayed.

Biofeedback Mode — displays signal intensity, initial reaction, ongoing reaction, coefficient of form, dose and zero indicators and time since tissue contact. The reaction is a measurement of reaction to the output pulse. The data is applicable when the frequency and number of pulses remain constant. Where the frequency and number of pulses change per preset conditions, the reaction changes, and thus the Ongoing reaction is invalid and is not shown. Biofeedback Mode applies to Relax Assess, Blue Relax, RSI, and AVA mode.

Frequency -- Hz. Rate of output pulse pattern.

Initial Reaction Reading (IR) — The relative measure of the body's impedance. High IR indicates areas to focus treatment.

Ongoing Reaction Readings (OR) — Used to determine treatment progress.

Coefficients are displayed as X and Y.

Coefficient of Ongoing Reaction (X) and Coefficient of Initial Reaction (Y) indicate the ratio of change of the body's ongoing response to the stimulation pulse. In a person with normal readings, Y should be greater than X.

If $X=Y$, no dynamic change. Thus, lack of response to stimulation indicates that the body may need more treatment at that area. This put simply means that the stimulation is not changing conductivity in the area; we should look at an electrolytic or a hydration problem.

If $Y \leq X$, a low dynamic change indicates that the body may need more treatment at that area.

If $Y \geq X$ the dynamic change indicates that the body is approaching satisfactory response to the stimulation.

Damping = Damping controls the shape of the output waveform. With increased damping, the output pulse amplitude is decreased and the pulse width is increased.

Dose = % of change based on a specific mathematical algorithm involving time which indicates that the first aspect of application is completed. This involves a % of change in the conductivity of the tissue. Tissue exhibiting normal conductivity and reaction, dose will happen before zero. In the case of dehydration and low electrolytes, zero may happen before dose.

Zero -- Indication that the second aspect of treatment is complete indicating that the output has reached optimum waveform or the ongoing reaction has stabilized.

Modulation — Change. The power is modulated or decreased and increased between the lowest power setting and the user-selected power setting. The modulation is displayed with the seconds power on at user selected power level; seconds power is off (lowest setting is 1 which is 0 power output). Power is ramped up and down for user comfort and the actual power level is displayed as it is modulated. Modulation options are 0:0 (not changed at all), 0.5:1, 1:1, 2:1, 3:1, 4:1, 5:1, 6:1.

Power Curves — Option to select the maximum power and power increase/decrease rate.

Pulse selection — Select the number of pulses in an output pulse packet.

Speed of Reaction — indicative of the speed of the body's response to stimulation. A higher response rate indicates increased local activity. When treatment is complete, the speed of reaction will indicate a "0" to signal that the second aspect of treatment is complete.

Z – Delay time between pulses within an output pulse packet.

THE BEST-RSI™ DEVICE



The Best-RSI™ device is classified and certified as Class II Type BF equipment. It was created for “symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-surgical and post-traumatic pain”.

Best-RSI™ Device Operating Modes

The device operates in four operating modes and Pause mode. The four modes of operation include:

Relax Mode: for general pain relief. Apply directly to the skin over the affected areas until the device “rings” or 20 minutes 2–3 times daily. Relax mode is sometimes applied to chronic conditions. Apply directly to the skin over the areas affected by chronic conditions until the device “rings” or at least 20 minutes two to three times daily. Typical treatment time in a given location is until a “longer” ring indicates positive treatment progress. This is usually between a few seconds and 15 minutes.

Deep Stimulation Mode: for micro-current stimulation. Apply directly to the skin 5 to 10 minutes 2 to 3 times daily. Typical treatment time is 5 to 10 minutes or longer as indicated. Treatment may be applied for up to one hour at a time every 3 to 4 hours.

RSI Mode: for chronic pain relief. Apply to areas of intense pain, or trauma over 24 hours. Apply directly to the skin 5 to 10 minutes 2 or 3 times per day directly over the area of pain or trauma. Typical treatment time is 5 to 10 minutes or longer as indicated. However, treatment may be applied for up to one hour at a time every 3 or 4 hours.

Acute Mode: for acute injury and for pain relief. Apply directly to the skin on areas and surrounding areas of contusions, lacerations, or abrasions. Apply directly to the skin on areas and surrounding areas for 15 to 20 minutes as often as hourly for relief.

Device Time Out: When the device settings are not changed for 60 minutes, the device becomes idle in Pause mode. To reactivate the device, simply press the (+) or (-) power switch one time, or turn the unit off and on again.

THE PRO-SPORT II II™ DEVICE

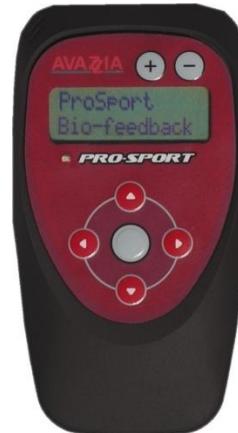
The Pro-Sport II™ device is a micro-current stimulator for:

- Massage therapy
- Relaxation
- Massage stimulation therapy

The device is not a replacement for professional health care.

The Avazzia Pro-Sport II II™ offers the best of Avazzia’s Biofeedback Electro Stimulation Technology and Avazzia Variable Advanced control options in a single device.

- Biofeedback



- Avazzia modes including Relax Assess, Blue Relax, Massage, Stimulate, Deep Stimulate, Blue Stimulate, Acute RSI, VASO, Acute Trauma, 783 Harmonics, Alpha 7 – 12, Beta 12 – 31.2, Delta 0.5 – 4.0, Gamma 37 – 43, Theta 3 – 8, Tone 1, Tone Plus, Tone Advanced, Tone Intense, PG 2500, HGH, AVA, VAZ 1, 2, 3, and 4.
- AVA (Avazzia Variable Advanced Mode)
- Power Curve choices of Normal, Cosmetic, Soft, Sensitive and Ultra Soft.
- Engineered and Manufactured in the USA

Avazzia

- Customer service in the USA
- US FDA company
- ISO 13485 international quality certification
- Patented technology with new patents pending
- Avazzia quality copyright and patented Comb and Y-Electrodes

BEST™ products provide interactive beep and ring tones to indicate when desired results are achieved and as measured amounts of time have passed. LEDs on the face of BEST™ devices indicate output is active.

The Pro-Sport II™ device is entirely noninvasive. It is a reflex biofeedback device involving no drugs and no surgery, only a light touch to the body with an electrical energy responding to the body's own signals.

The technology for this device was developed by the same engineer that designed the chips for the first lunar landing module that now sits in the Smithsonian Institute. Mr. Tim Smith and his team sought a method of treatment that was energy efficient, portable, and noninvasive, circumventing the need for costly pharmaceutical or surgical intervention and its unwanted side effects when possible.

The device works on acute, chronic, chronic exacerbated, and intractable pain of every sort, by acting systemically on the energy field of the body. Yet it is the size and shape of a small TV remote control and operates on two ordinary AA batteries. Only minimal training is necessary to use it for enhanced wellness through:

- Massage therapy
- Relaxation therapy
- Massage stimulation therapy
- Cosmetic effects such as increased facial tone (the natural facelift)

Russian trials have demonstrated dramatic benefits for pain relief with their SCENAR therapy. Avazzia BEST™ devices produce electrical signals substantially equivalent to SCENAR devices. Victims of both fractures and various other injuries have experienced more pain relief from the release of natural opiates stimulated by this form of BEST™ therapy than from chemical opiates administered pharmaceutically.

During treatment, the recipient feels only a gentle tingling or stroking sensation, as the device is run over the spine, abdomen, affected area, or other relevant portions of bare skin. The device sends electrical signals, records the resistive response, and uses its electrical feedback; and it uses software to analyze data from the signal and report to the physician through a digital display. The practitioner determines where to apply the device by looking for anomalies on the skin surface, indicated by redness, numbness, stickiness, or a change in sound from the device. These areas may not seem to be directly related to the symptoms for which treatment is sought, but the

experience indicates that improvement process is commenced by treating these asymmetries or active zones.

How BEST™ Devices Work

The desired treatment mode is selected and the device is placed on the skin. The user then sets the desired signal intensity.

As the device sends signals through the skin, the electrical properties of the tissues change. An electrical feedback loop is established between the tissue and the device. As the electrical properties of the tissue changes, the feedback loop modifies the next feedback signal. This feedback is between tissue (bio) and an electrical circuit; hence, biofeedback. This signal is measured by a computer within the device and various results are reported to the practitioner.

A search of peer reviewed and published literature reveals another aspect of the device involving neuropeptides, the internal pharmacy of chemicals by which the body is kept in physiological balance and return to homeostasis is achieved. Without the activity of regulatory peptides produced by the nerves, the body can't adapt to disease states, which may be caused by injury, injection, or toxicity. The device stimulates the nervous system to produce its regulatory peptides, thereby prompting the body to achieve "balance" or "homeostasis." The device catalyses the production of neuropeptides for use where necessary to re-establish the body's natural physiological state and cause a return to normalcy. Because these peptides last up to several hours, the process continues long after the treatment is over.

The healing process is ongoing for another reason. Disruption occurs where portions of the body have been blocked from communication with the energetic system that keeps it in balance. The device begins a dialogue with these blocked areas. Once the lines of communication have been re-established, the information-starved areas keep on talking. They want to stretch and move and come back to life. Normalcy is reported not only in the nervous system but in conjunction with other chemical imbalances, correcting sleeplessness, appetite, behavioral problems, learning ability, memory, sexual function, and overall physical health.

As for the principles behind BEST™ treatment, the body has a finite amount of energy that must be divided among multiple functions. It's most essential survival functions are energy replacement (feeding), reproduction, and the fight-or-flight response. Injuries need to be repaired, but only sufficiently for the organism to maintain its survival functions. When repair reaches that level, the stressed organism with insufficient energy for all its needs abandons the healing process and returns to eating, reproducing, and fleeing enemies. The device works on an informational level to remind the body that it still has repair work to do.

Why It Works

The body is continually influenced by external stimuli, which it reacts to in a way that maintains internal balance, or homeostasis. Because these stimuli are infinitely variable, no two stimuli are experienced in the same way. But pathological signals are experienced as repetitive, so the body adapts to them and fails to recognize it has a problem. The pathological vibratory signal becomes self-perpetuating and gradually spreads, leading to organ dysfunction. The Pro-Sport II™ device modifies the pathological signal so the brain becomes aware of it, inputting electrical impulses that are never the same and cannot be adapted to, forcing the body to respond.

Central nervous system involvement is reintroduced by neuropeptides that alter the regulatory pathway, breaking the repetitive pathological cycle and allowing cellular and organ recovery. The result is markedly reduced healing times and pain relief.

Research and Contraindications

No unwanted side effects have been experienced from SCENAR or BEST™ treatment in over twenty years of use in Russia and Europe. The impulses sent by the device are similar to the body's own nerve impulses and are quite safe, even for children. The only absolute contraindication is for people with cardiac pacemakers, although certain other pain and discomfort from diseases and injuries should be treated only by a practitioner with thorough training.

As with all natural treatments that stimulate rather than suppress the body's own healing power, the initial effect may be a healing crisis that makes the patient feel worse before feeling better. A lack of energy or general malaise may result as old problems are brought to the surface for treatment and elimination. But this necessary bit of housekeeping soon passes and is followed by new heights of well-being, increased energy, and more refreshing sleep.

Pacific Health Options' own experience indicates that for long-lasting effectiveness, chronic problems may need treatment three or four times a week for up to six weeks. Acute problems, however, often resolve after only one or two treatments. Fresh injuries or acute inflammatory processes may require intensive treatment once or twice daily for several weeks, reducing gradually as the condition improves.

Protocols

Pacific Health Options Inc. has developed specialized protocols to establish guidelines and direct treatment with reliability and ease. These protocols have been established to address specific and general soft tissue dysfunctions, which are acute or chronic in nature. Treatment with the Pro-Sport II™ device combines very well with physical and occupational therapy, as well as most therapies aiming for rehabilitation after illness, surgery, or trauma.

Pacific Health Options' involvement with athletic trainers and sport medicine specialists in the US and Europe has shown that this technology integrates perfectly with the principles of therapeutic exercise.

Please contact Pacific Health Options for additional information.

Clinical Effectiveness

Developers and promoters of SCENAR Technology have reported significant returns in clinical environments with impressive statistics being shown.

- 79% decrease in average pain scores after 3 treatments in severe chronic orthopedic pain patients. 68% of subjects achieved complete pain relief. (Pilot study of 22 patients, Gerhard Maale. 2005)
- 100% of sports knee injury patients achieved a reduction of greater than 2 points on the pain scale and a return to full sport participation for 98% of patients. (Review of 19 patients presented at the International Congress on Sports Rehabilitation and Traumatology, Italy. Stephen Coleman, BSc. 2005)
- 98% of patients achieved a pain relief of greater than 2 points on the pain scale for a combination of acute and chronic conditions. 53% of patients achieved total relief. (Retrospective review of 129 patients prepared for CE mark Technical file, 2004)

Basic Introduction to BEST™ Technology

Best-RSI™ and Pro-Sport II™ devices are electrical devices that utilize specific features of Avazzia powered technology.

The device produces biphasic impulse current. It produces bipolar impulses with variable parameters that are controlled directly by the reaction of the organism during the treatment in accordance with electro-dermal impedance (galvanic skin response). Technical methods and digital processes (particularly biological feedback) provide individually dosed influence on human skin areas in order to help the organism restore its lost function(s).

The device uses the following main modes:

- Subjective, in which the time of treatment is regulated by the therapist according to given guidelines.
- Dosed mode which regulates the time of treatment for one spot/area automatically. Visual and audio signals indicate the end of a dose delivery (DOSE “D”), and again at ZERO (Z).
- The device is intended for general practitioners, therapists, and medical staff. It can be used in medical-preventive establishments, hospitals, ambulances, and at home by properly trained nonmedical individuals.

Therapeutic Goals

BEST™ therapy is focused on providing relief from acute, exacerbated, chronic, and intractable pain, without side effects.

Limitations or Contraindications

- Those with cardiac pacemakers
- Those with cardiac fibrillation
- Intoxicated individuals
- Personal intolerance
- People suffering from severe mental disorders
- Pregnant women
- People with organ transplants

PRO-SPORT II II™ BIOFEEDBACK ELECTRO STIMULATION TECHNOLOGY

The Pro-Sport II II™ device is a unique neurostimulation device. All cells and tissues in the body function within a normal range of electrical activity. The skin has also presented fascinating electrophysiological behaviors. Extensive work has been done to map the electrical conductivity characteristics of the skin relative to internal functions. Both somatic and visceral dysfunctions are reliably projected into the skin. These projections are detectable by significant changes in the electrical conductivity of the skin. As long as the stressful stimulus remains in place, the patterns of altered conductivity can persist for weeks, months, and longer, creating the chronic pain pattern.

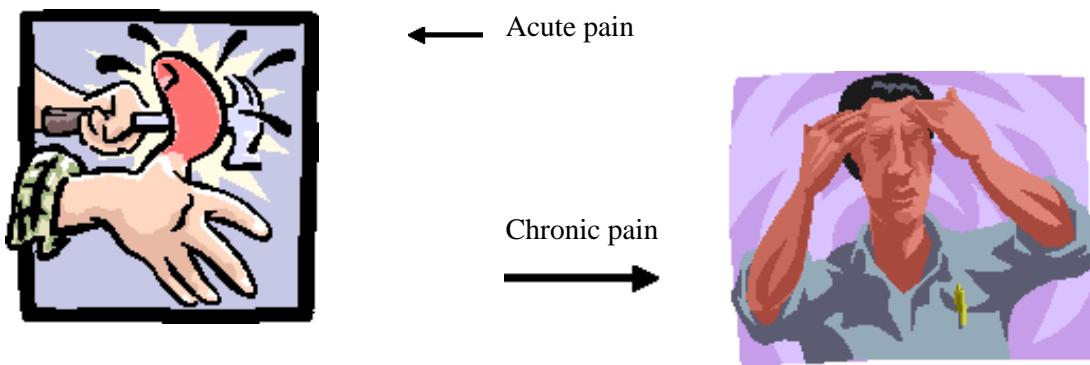
The device is designed to sense this activity and, through a process of biofeedback, to stimulate the tissue in its self-regulating processes.

The outcome of the Biofeedback Electro Stimulation Technology is neurostimulation that affects the area of pathological activity locally through an increased blood circulation, neuropeptide release, stimulation of the lymph flow, muscle relaxation, and centrally, by affecting the CNS, in particular the autonomic nervous system.

The operator of the Pro-Sport II™ device has the choice of a variety of modes when using the device. If desired it is possible to view aspects of this interaction on screen through sets of numbers and symbols. The device is capable of signaling to the operator when specific results have been achieved. All reactions are real-time and continuously changing according to the body's responses to the impulses. It is also possible to work more freely without attention to the screen and assess the results through easy-to-recognize signs in the tissue response itself.

Body Basics for Pro-Sport II™ Therapy

Although much progress has been made, pain itself is still much of a mystery in modern medicine. Strangely it is possible to feel pain without any actual injury or damage to the tissues. Certainly, pain is a neurological process, but, it also is an emotional experience; it conjures up memories of past painful events. The experience of pain varies from individual to individual and from culture to culture. As such, pain is defined as an unpleasant sensory or emotional experience connected with actual or previous damage or psychological suffering.



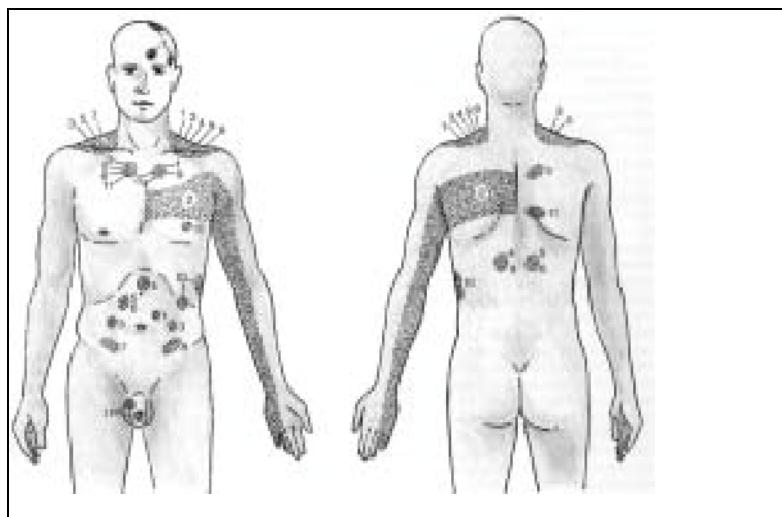
Pro-Sport II II™ therapy is a form of neurostimulation that utilizes a unique Biofeedback Electro Stimulation Technology process. The device is applied directly to the skin and treats a wide variety of pain complaints. Understanding some of the relationships between the skin and the internal functions of the body is helpful in appreciating Pro-Sport II II™ techniques.

The skin is more than an external barrier to the outside world. The skin has numerous dynamic functions, one of the most important being communication. It is helpful to understand that the skin and the nervous system share a common embryological source.

The ectoderm is one of three germ layers of the developing embryo and gives rise to the tissues of both the skin and the nervous system. It is thought that this common origin may explain at least some of the reasons why therapies that stimulate the skin and its associated tissues may have such a significant effect on so many internal functions. In a way, the skin can be visualized as an extension of the nervous system towards its environment. The skin and the nervous system remain functionally linked throughout life.

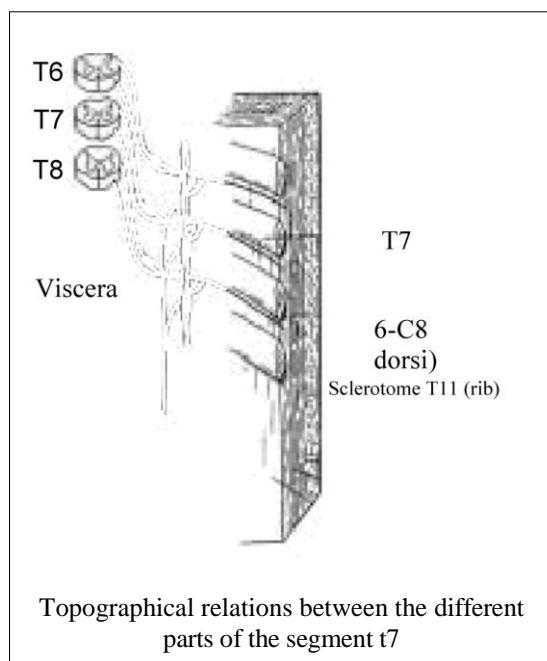
Environmental signals affect the skin, and this signal information is passed through the neural pathways to various parts of the body including the central nervous system. The movement of information however is not just from the outside skin to the inside of the body. There is also

information flowing from the inside of the body out to the skin. As long ago as the end of the 19th century, it was recognized that the internal organs of the body projected themselves into the skin as predictable reflex patterns. The Projected Reflex Zones of Zacharin-Head are standardized areas on the skin in which organ dysfunction can be recognized.



Other expressions of internal physiology can also be found in the skin. Segmental organization is one of the most fundamental designs in all creatures.

The body is organized along the spinal cord with a series of segments each supplied by a specific spinal nerve root. One particular nerve root will supply a family of tissues that remain forever related to each other because of the common root. Consequently, an organ, some part of the skeleton, certain muscles, and of course, specific areas of the skin all share common influences. Because the skin is the most easily accessed of these tissue groups, it offers a simple gateway to many hidden functions.

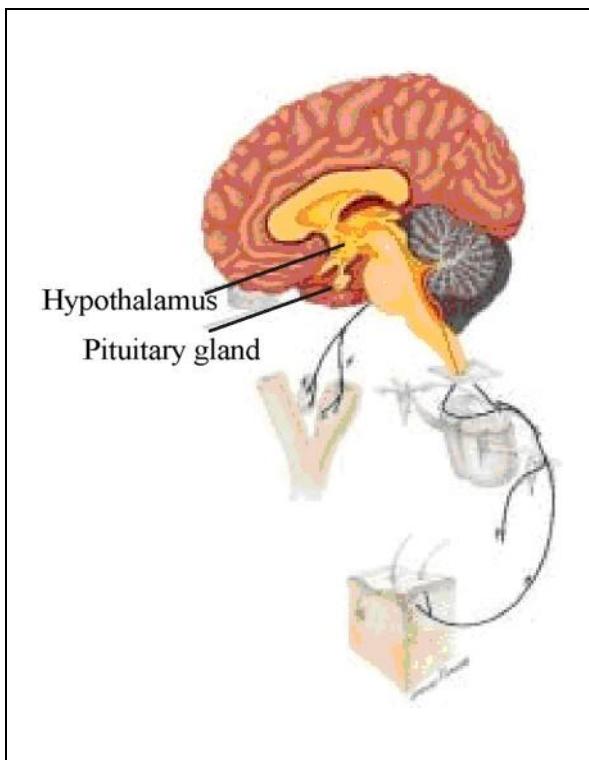


The skin has also presented fascinating electrophysiological behaviors. Extensive work has been done to map the electrical conductivity characteristics of the skin relative to internal functions. Irvin M. Korr (PhD Biology, Princeton) and others have demonstrated that both somatic and visceral dysfunctions are reliably projected into the skin.

These projections are detectable by significant changes in the electrical conductivity of the skin. Interestingly, these patterns of altered conductivity can come and go within minutes if the irritating stress is applied and then withdrawn. On the other hand, if the stressful stimulus remains in place, the patterns of altered conductivity can persist for weeks, months, and even longer.

Neurological research has continued to examine the complex interactions involved in the mediation of pain. The relationship between the peripheral tissues of the body and the central nervous system (CNS) remains the focus of many pain management studies. Sensory input from the skin has a strong influence on many levels of the CNS including the intermediate levels of the brain. The role of the hypothalamus in the regulation of autonomic, endocrine, and biochemical processes is profound, and stimulation of the skin appears to be able to influence the functions of this key CNS structure.

The hypothalamus is a vital control center for survival and the optimal performance of the body.



- Homeostasis/homeokinesis control center
- endocrine functions (e.g. hormones)
- autonomic functions (e.g. sympathetic and parasympathetic)
- neurochemical effects (e.g. dopamine, serotonin)
- controls emotions like satiety, hunger, body temperature (e.g. sweating), osmosis (e.g. urination) and reproductive behavior
- regulates sleep and wakefulness, feeding, and sexual activity
- coordinates somatic motor control, visceral control, and hormone release

Pro-Sport II™ Applications

- Symptomatic relief and treatment of chronic expressed pain
- Relief for treatment of post-surgical and post-traumatic pain
- Added therapy for reducing pain and the symptoms associated with osteoarthritis
- Relaxation of muscular contractions
- Increase of localized blood circulation
- Post-surgical stimulation of calf muscles in the prevention of venous thrombosis
- Muscular reeducation
- Maintenance or increase of movement
- Prevention or delaying of atrophy caused by immobilization
- Reduction of muscle spasms

TERMINOLOGY

Active Zone: Or Active Site -- An area of the skin that is different from the surrounding skin. Indications of an Active Zone include:

- Color
- Sound
- Stickiness
- Sensitivity of the skin
- Primary signs

Point of Pain: An area of pain or dysfunction found on the skin.

Color: When the device is moved over a point on the skin, the color of that point or area may change. One spot may become redder even though the entire area is being stroked the same way. A redder or paler area is a sign of an Active Zone.

Sound: Because the Pro-Sport II™ device is designed to make a buzzing or humming sound when it is moved along the skin's surface, an Active Site can be detected by sudden changes in the sound of the device. When the electrodes go over the spot, the sound can become louder or quieter. A change in the sound of the device when run over certain spots will indicate an Active Zone.

Stickiness: When the electrodes are moved along the skin's surface, certain spots can become sticky compared to the area in general. Whenever you move the electrodes over an area of increased resistance to movement, the device might get stuck or seem glued to the skin as you attempt to slide it over the area. This stickiness is a sign of an Active Zone.

Sensitivity: The patient may feel a little more uncomfortable whenever the device is moved over certain areas of the skin. In certain cases, the spot may feel less sensitive than the surrounding area. This change in sensitivity is the sign of an Active Zone.

Primary signs: In certain cases, there could be small changes to the spot even before treatment begins. There could be itching, redness, dryness, texture differences, etc. These are primary signs. These signs indicate an Active Zone.

Note: Several signs indicating an Active Zone could show up at the same spot. They could include color and sound, color and stickiness, etc. In the case of stickiness, treat in the direction of the maximum stickiness without paying attention to other signs that may appear.

Pro-Sport II™ Diagram

Diagram – Top side

1. Power on/off slide switch
2. Power control keys
3. Accessory Port
4. Display
5. Output Indicator LED
6. Menu navigation keys



- a. ▲ - navigate up key
- b. ▶ - navigate right key
- c. ▼ - navigate down key
- d. ◀ - navigate left key
- e. ☐ - SELECT key

1. Electrodes



1. Onboard built in electrodes on back of unit – The electro-massage pulse is applied through the electrodes on the back of the unit.
2. Battery connectors – The device uses two AA 1.5 V batteries. Use good quality batteries.
3. Serial number
4. Calibration/programming connector

Note: Contact Avazzia for calibration service annually.

The Screen in DEFAULT Settings

Power on the Pro-Sport II™

After a few seconds, the following parameters appear on the screen:

- Power Level Indicator
- Chronometer
- Relax Assess



Power level display on screen:

When the device is switched ON, the power level is displayed in the top left-hand corner of the screen and remains visible throughout the treatment regime.

Power level of the device:

The Power level is energy output from the device per second.

To increase power, press (+)button. To reduce power, press (-) button.
Minimum is 1. Maximum is 250.

Power level descriptions:

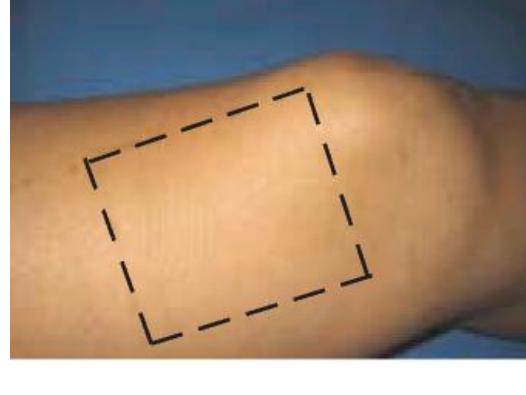
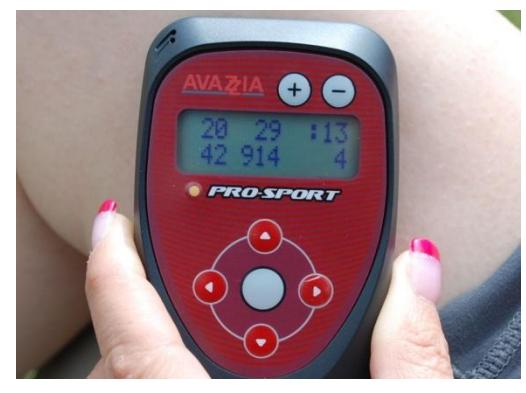
- the below-threshold level, there is no subjective sensation;
- the threshold level is sensed as a slight vibration;
- the above-threshold level is sensed as comfortable electro-action and is most frequently used;
- the supra-threshold level is sensed as painful electro-action.

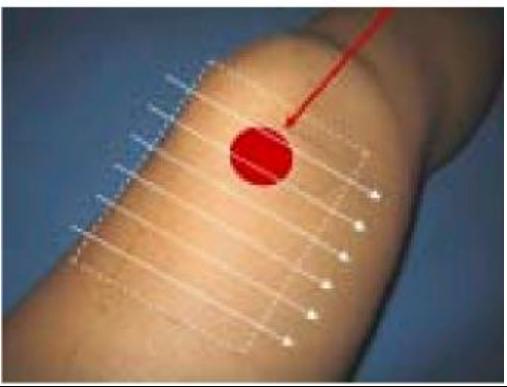
Basic power levels in practice:

- use higher power levels for acute pain or an emergency;
- use comfortable power levels for chronic pain.

BASIC INSTRUCTIONS

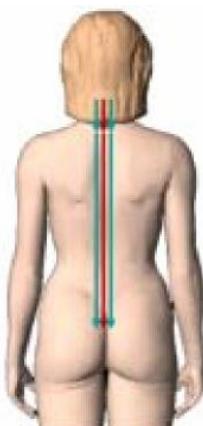
In this first exploration of the Pro-Sport II™ device we will simply use the On/Off function and the Power UP/Power DOWN function. We will leave every other possible setting in the factory default condition.

<p>Step 1: Outline the area where you are intending to work.</p>	
<p>Step 2: Use the slide switch to turn your device ON.</p> <div data-bbox="409 994 817 1157" style="background-color: #d9e1f2; border-radius: 10px; padding: 10px; text-align: center;"> 1 :00 Relax Assess </div>	
<p>Step 3: Place the device on the skin outside of the intended area of treatment. Press the (+) button to increase the level of power until the patient feels a comfortable pricking sensation.</p> <p>For further adjustment of the power please look at the page explaining when you should use higher or lower levels of power.</p>	
<p>Step 4: Start to steadily and firmly move the device, applying pressure in one direction only. Keep the electrode lengthwise. Move the device from top to bottom as in painting towards your right.</p>	

<p>Step 5: As you are moving the device, look for the differences:</p> <ul style="list-style-type: none"> • stickiness of the skin • the appearance of redness and sometimes paleness • the sound from the device (quieter or louder) • the patient's sensations (could be more sensitive in some areas than others) 	
<p>Step 6: When you detect those differences, keep the device steady on the area for 1 or 2 minutes. During this time the device will be establishing biofeedback balance.</p>	
<p>Step 7: Try to move the device over the position where you detected the earlier difference. If you still detect any stickiness or other differences, paint in four directions in the following order:</p> <ul style="list-style-type: none"> • top to bottom • right to left • left to right • bottom to top <p>until you feel a comfortable sliding sensation when moving the device.</p>	
<p>Step 8: Reset your device to default settings, but keep the same level of power. When there is a change (dynamics) in the originally detected differences, you can stop the treatment.</p>	

Practicing on the back

Now that we have a basic experience of finding and treating our own arm or leg, let's try the same approach on the back of a student partner. One of the easiest to access yet powerful areas of the body in reflex style BEST™ therapy is the back.



The back is the main location of the Spine Zone, which is the main General Zone of BEST™ therapy.

Step 1: The patient should be sitting up in a comfortable position, exposing the whole length of the spinal column. Before commencing, observe the whole spine and muscle development, noticing any abnormalities. Palpate the muscles which are either in spasm, in atrophy or other pathological state. Palpate the whole spinal column finding most sensitive areas.



Step 2: With a marker, circle the vertebra C7; this will be your starting point.

Step 3: Prepare the device to work: turn the slider switch **ON** on the side of the device.

Step 4: Outside the area intended to treat (on the shoulder) place the device and increase level of **POWER** by pressing the button **(+)** until the patient is experiencing a comfortable prickling sensation.



Step 5: Place the device on the center of the back, just below C7 and slide very slowly down, positioning the device right on the spinal processes. As you work down the spine, you can alter the **POWER** level if necessary.

Step 6: As you are moving the device, look for changes in the tissue response. Examples of differences:

- stickiness of the skin
- the appearance of redness (sometimes paleness)
- the sound from the device (quieter or louder)
- patient's sensations (could be more sensitive in some areas than others)

Step 7: Apply continuous stimulation with the Pro-Sport II™ device, moving down very slowly until you reach the coccyx and then continue from the hairline down to C7. Stop just above C7. Paint in the same way a few times (for example, three times).



Step 8: When you detect differences, keep the device steady or you can change one of the parameters (the best combination to pick will be explained later). Once you have programmed your device to certain settings, keep the device steady on the area for one or two minutes. During this time the device will be establishing biofeedback and correcting the body's signals.

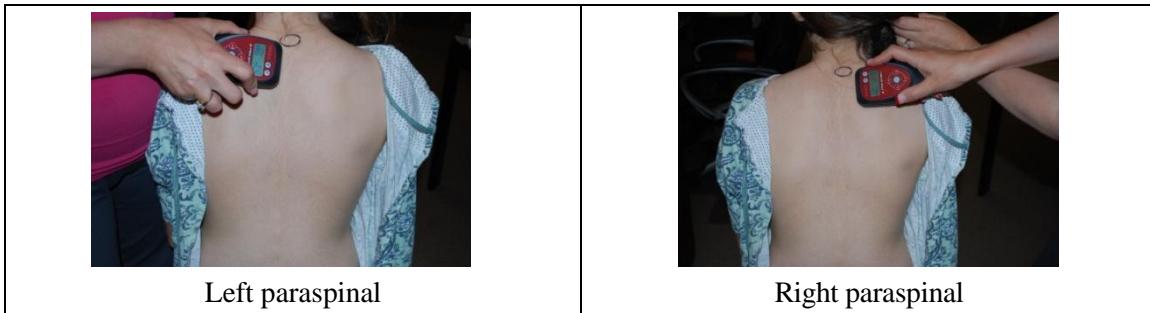
Step 9: Try to move the device over the position where you detected the difference. Then paint in four directions in the following order:

- top to bottom
- right to left
- left to right
- bottom to top

Continue until you feel a comfortable sliding sensation when moving the device.

Step 10: Reset your device to default settings, but keep the same level of power. When there is a change (dynamics) in the originally detected differences, you can stop the treatment.

Step 11: When you complete painting down the back, paint in the same fashion on both sides of the paraspinal zone.



Relax Assess and Painting Sticky Spots

The Pro-Sport II™ device has 11 basic categories or modes of use. One category is the **Relax Assess** mode. We will see how to apply the other categories later.



The Relax Assess mode is used in a more objective manner and is used for evaluation and treatment of a point of pain, either acute or chronic. Upon mode selection, the first line displays the power level and time duration. When the electrodes are placed on the body, the level of stress in the area is displayed.

Basic information in Relax Assess Mode



When the highest level of stress in a zone is located (the highest IR reading), leave it on the area without moving. The Assess will give way to D for Dose. Dose is a sign (bell) to the operator indicating that the body's response to the stimulation is beginning to enter the functional physiological range (95% correction).

Basically, a Dose is the indication that the main aspect of the treatment has been successfully completed.

This will be followed by a “Z” for Zero. A Dose usually comes first and is followed by a Zero. This Dose/Zero sequence indicates that the body activity has entered the functional physiological range and has stabilized in that range. If the Zero appears before the Dose, this indicates that the body activity has become fixed and is no longer responding dynamically to the device. Set the device to **Deep Stim** for one minute on the point.

The Pro-Sport II™ device interfaces with the functions of the body through contact with the skin. It is a principle of BEST™ therapy that disturbances within the body project into the skin and are detectable by changes in the physiology of the skin. Furthermore, stimulation of these skin projections is recognized as having beneficial effects on the internal functions related to the projections. At times the skin projection is very closely situated to the site of dysfunction and may even be directly over the dysfunction itself. Surprisingly at other times, the skin projection may be located at some distance from the dysfunction.



Detecting active projections in the skin is a fundamental feature of the techniques associated with the Pro-Sport II™ therapy. In BEST™ terminology, the area of the skin in which the active projection is located is known as the Active Site. An active projection in the skin is often referred to as an asymmetry and more specific sites are called small asymmetries. We will refer to the phenomenon as the Active Site.



An Active Site is recognized in a number of ways. Most simply, the Active Site stands out because it is unlike the surrounding area of skin. With just a visual exploration of the back for example, is there any spot that stands out as being different?

Do you notice a color difference or perhaps a rash?

Is there a patch of skin that is particularly dry or has an unusual texture?

Active Sites

These are all indications of some change in the local physiology of the skin and are evidence of a possible Active Site. In any of the examples just given, it is possible that an internal functional challenge is being displayed or projected out and on to the skin.

As we have seen earlier in our first practice session, evidence of an Active Site can be elicited using the Pro-Sport II™ device. When the device is moved slowly and firmly along the skin's surface, different responses start to become apparent. One spot may become redder even though the entire area is being stroked in the same way. Sometimes the opposite is seen. As a larger area becomes redder, one spot does not become red and is pale by comparison. One of the most popular ways of detecting an Active Site is to search for spots that are sticky compared to the area in general. At times the stickiness can be quite dramatic. It actually seems like the device gets stuck or even glued to the skin as you attempt to slide it over the area.

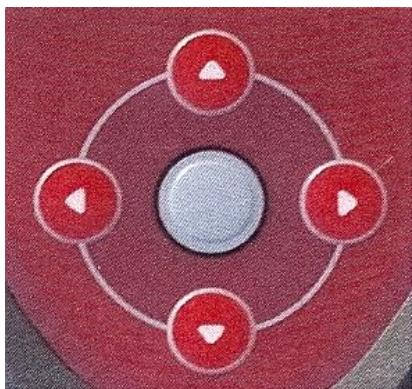
Because the device is designed to make a buzzing or humming sound, an Active Site can be detected by listening to sudden changes in the sound. An unusual increase or decrease in the sound points to the possibility of an Active Site. Lastly, as you slide the device evenly along on the skin, any spot that feels tender, painful, or even numb is evidence of a probable Active Site.

The Pro-Sport II™ device is also designed with features that give you evidence of an Active Site using measurements related to the conductivity of the skin to the electrical signal of the device. Fundamentally, the tissue at Active Sites is recognized as having altered impedance. There are several Pro-Sport II™ techniques that seek out evidence of Active Sites using measurements of tissue conductivity. It is important to understand that the readings of the device are values representing complex interactions of which skin resistance is but one factor. Pro-Sport II™ readings are values of merit and express the consolidation of a number of electrical related physiological responses.

When searching for an Active Site, findings are based on a set of comparisons. The comparisons are made easy by performing some kind of stimulation with the device that elicits a response. Stroking the skin and watching for stickiness, redness, sound changes, and significant sensations are examples of comparison techniques. The measurement of electrical skin responses elicited by the device is also an example of a form of comparison.

An Active Site can be rather temporary or very long lasting. Because the body is highly responsive to stimulation, an Active Site can quickly emerge in the skin as a result of some type of stress or irritation to the body. An acute injury for example rapidly develops changes in the physiology of the skin resulting in the formation of an Active Site. This fact is easily confirmed using the electro conductivity measurement features of the Pro-Sport II™ device. It is also true that an Active Site can persist for weeks, months, and possibly even years at a time. Chronic pain complaints associated with both somatic and visceral conditions are well known to present Active Sites of long duration.

PRO-SPORT II™ CONTROLS



The Menu Navigation keys include:

- ▲ - Navigate Up Key
- - Navigate Right Key
- ▼ - Navigate Down Key
- ◀ - Navigate Left Key
- - Mode Select Key

Depress the Navigation Arrow keys to navigate to the desired operating mode. Then depress the Mode Select key to select the desired operating mode.

Introduction to Basic Treatment Settings

We will now explore the various settings that are possible while in the Treatment mode. Although there are literally hundreds of possible variations using each of the settings, expert practitioners find that there are a limited number of combinations that form the core of their work.

First before examining the various treatment combination recommendations, let's see how to find each setting and navigate between them. Keep an eye on the screen and you will notice that access to the various Treatment settings is easy with just a little practice.

By pressing the ▲ **Navigate Up** button you can access a screen menu with different setting categories and their specific choices.

By pressing button ▲, we will set the device to AVA. By pressing the Center control, the AVA mode is activated. By pressing the ►, you will have the ability to control modes such as: Frequency, Number of Pulses, Z Value, Damping, and Modulation.

Power Curve settings:	Normal	}
	Cosmetic	
	Soft	
	Sensitive	
	Ultra Soft	

These settings permit an ultimate comfort in the sensation of the device's power settings.

This is what your Navigating Menu looks like.

Main Mode Menu		
< Biofeedback Mode	^ and v	> Submenu options
Default Biofeedback<	Relax Assess	➤ Power Curve
Default Biofeedback<	Blue Relax	➤ Power Curve
n/a	Massage	➤ Massage with modulation 0.5:1, 1:1, 2:1, 3:1, 4:1, 5:1, 6:1
n/a	Stimulate	➤ Power Curve
n/a	Deep Stim	➤ Power Curve
n/a	Blue Stim	➤ Power Curve
n/a	Acute	➤ Power Curve
RSI w/Biofeedback<	RSI	➤ Power Curve
n/a	VASO	➤ Power Curve
n/a	Acute Trauma	➤ Power Curve
n/a	783 Harmonics	➤ Power Curve
n/a	Alpha 7 - 12	➤ Power Curve
n/a	Beta 12 – 31.2	➤ Power Curve
n/a	Delta 0.5 – 4.0	➤ Powe Curve
n/a	Gamma 37 - 43	➤ Power Curve
n/a	Tone 1	➤ Power Curve
n/a	Tone Plus	➤ Power Curve
n/a	Tone Advanced	➤ Power Curve
n/a	Tone Intense	➤ Power Curve

n/a	PG2500	> Power Curve
n/a	HGH	> Power Curve
AVA w/Biofeedback<	AVA	> Power Curve > Frequency > PULSE > Z Value > Damping > Modulation
Biofeedback when available	VAZ 1 VAZ 2 VAZ 3 VAZ 4	

Once in AVA mode you will have access to a whole world of programs that will enhance your treatment protocols. Learning how to best use the signal variations will be described on the next pages.

Pro-Sport II™ Settings in AVA



PULSES = Pressing ▲ button repeatedly will change the number of impulses in a packet from 1:1 to 30:1.

FREQUENCY = Pressing the ► button will take you to the default frequency (factory preset) of 59.35 Hz. Pressing the ▼ button will take you to 0.50 Hz. Pressing the ▲ button will allow you to choose your frequency setting incrementally up to 1565 Hz.

Z Value= Pressing the ► button will change the time between pulses in the sets (001 to 100 multiples of 20 microseconds between pulses within an output pulse packet).

DAMPING = By pressing ► button repeatedly you will arrive at Damping. This control will change the form of the impulse from 0 to 7 by using the ▲ button.

MOD = By pressing the ► one more time you will arrive at MOD which permits you to modulate your signal at 0,5:1, 1:1, 2:1, 3:1, 4:1, 5:1, 6:1. This means that your device will be active for the selected period of time punctuated by a 1-second pause.

Setting Combinations

Because the Pro-Sport II™ device is designed with a highly responsive interactive feedback, there are no absolute setting choices. Expert practitioners find that creative combinations often yield excellent results. The following is a list of combinations and general indications that may serve as a reference when considering choosing setting combinations in the subjective mode of the Pro-Sport II™ therapy.

Subjective Combinations in AVA Mode:

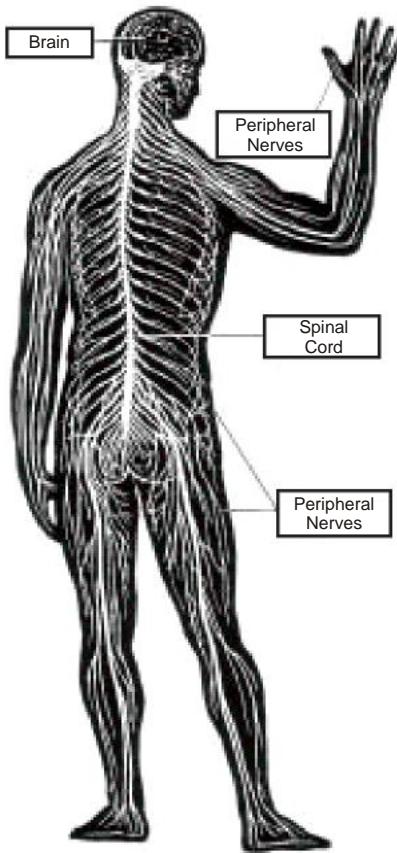
PARAMETERS	ACUTE SETTINGS			CHRONIC SETTING		DEFAULT
	I	II	III	I	II	
Pulse	5:1	OFF	OFF	OFF	Stimulate	OFF
DAMPING	2	OFF	OFF	4	Deep	OFF
INTENS	1	8/7	8	1	Stimulate	
Z	20	80/70	10	20	20	20
FREQ	352.1	59.35	59.35	15	****	59.35
POWER	High	High	Minimum	Low	Low	Comfortable

Pain and the BEST™ Devices

The body is organized to both sense and limit the experience of pain. This naturally occurring process is generally known as the Endogenous Neuromodulation System. In a biofeedback treatment of pain, the device works in cooperation with this innate biological function.

In simple terms, there are two major overlapping theories of how the body manages and limits pain. The first is the modified *Gate Theory*, which is an evolution of the neurological concept originating from the 1960s work of Melzack and associates. This first theory focuses primarily on neurological mechanisms. The second is the broad theory of endogenous opiate-like substances secreted by various tissues within the body. This second theory focuses primarily on biochemical processes. Although it remains to be confirmed, there is significant evidence that the Pro-Sport II™ acts in relation to both of these theoretical mechanisms.

C-Fibers & Neuropeptides



An examination of the nervous system reveals a very high ratio of small diameter nerve fibers. This fact is significant when exploring the experience of pain and the effects of the BEST™ technology. Basically, pain impulses travel into the central nervous system at different rates depending on what nerve fiber is stimulated. Thin myelinated A-delta fibers conduct noxious sensation quickly and very thin, unmyelinated C-fibers more slowly. Most pain sensation is delivered to the central nervous system by C-fibers. Interestingly, 70% of the peripheral nervous system is composed of these small-caliber, pain-transmitting fibers, which illustrates the high priority the organism places on this type of information.

Furthermore, most of the peripheral autonomic activity utilizes slow C-fibers. For example, the cranial cervical sympathetic node has been subject of considerable study and in humans it is composed of approximately 80% C-fibers. In higher mammals such as cats, the number of C-fibers in the Vagus nerve was 90% and in the pelvic nerve was 50%. C-fibers have a high threshold of excitement. The force of current required to activate C-fibers is many times higher than for A-fibers. Because the device generates a unique, high amplitude voltage impulse, it is expected that it is capable of stimulating small-diameter nerve fibers in general and the C-fibers in particular. This stimulation allows for an interfacing with numerous related functions including pain management.

Neurological effects of the device will occur in three interrelated groups of functions: local, segmental, and general.

When local actions occur, the responses will include:

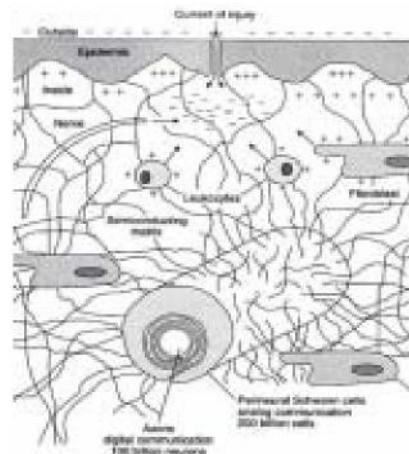
- the activation of afferent sensory nerves
- influences on local blood flow and related bioactive substances (and)
- the release of endogenous regulators of inflammation and the immune response

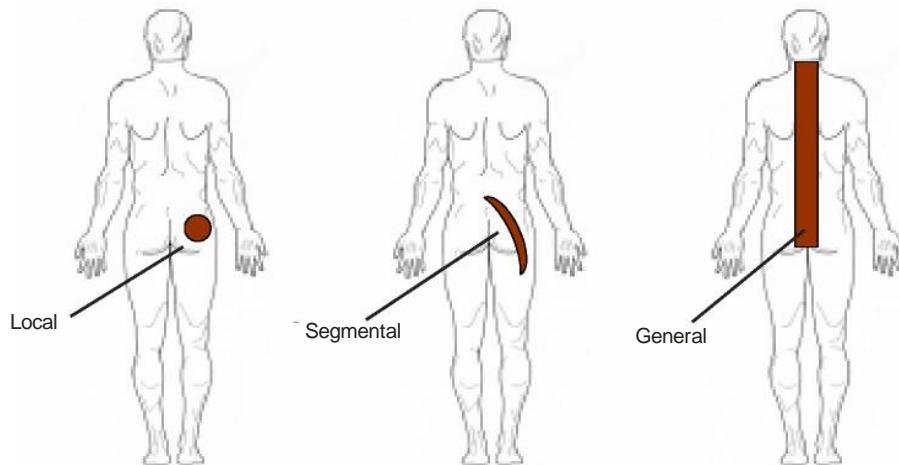
When segmental actions occur, the responses will include:

- influences on all the tissues related to each other within the primary stimulated segment including the visceral and somatic structures
- interactions with other segments that are indirectly related to the primary segment

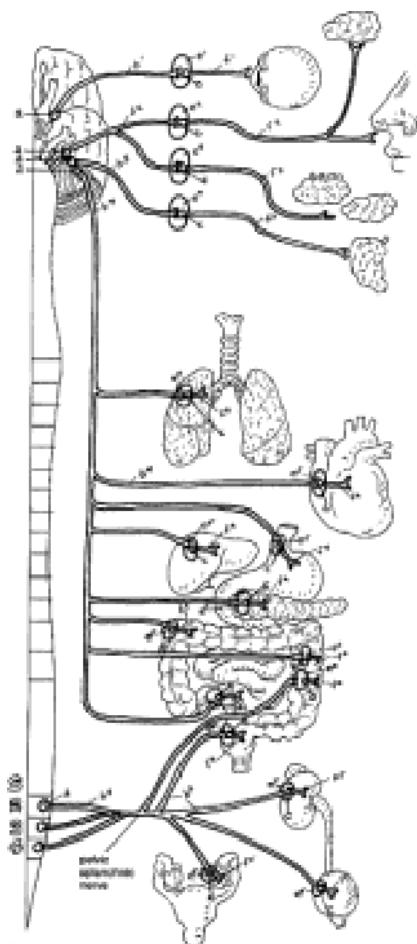
When general actions occur, the responses will include:

- influences in the autonomic regulation of vegetative functions
- influences upon the endocrine functions throughout the body (and)
- the activation of a broad range of regulatory peptides affecting numerous functions at every level





The generation of neuropeptides is well known to take place in the hypothalamic-pituitary-adrenal axis. Current studies have confirmed that neuropeptides are also produced in a variety of nerve tissues and other cells throughout the body. Because of their profound influence on self-regulation, these neuropeptides are frequently referred to as regulatory peptides. In some cases they have also been called information molecules because of their primary role in conveying the information commands required for countless physiological functions.



Regulatory peptides have the ability to create complex chains of molecules that result in cascades of biologically active compounds with a surprisingly long life span. The breakdown of these regulatory peptides is not just a simple act of decomposition but instead results in a synthesis of an entirely new bioactive compound. This new bioactive compound has a different function than the original target function. Interestingly, these compounds yield effects that are quite distant from the tissues in which the initial regulatory peptides were produced. These effects may even include actions upon genome activity. The most important property in the distant effect of the regulatory peptides is their ability to trigger the release of other new regulatory peptides.

Regulatory peptides are found in both the central and peripheral nervous systems and are generated in the somatic and autonomic branches of the peripheral. These bioactive compounds are released in response to adequate stimulation such as supplied by the device and have a specific effect on the surrounding local tissue as well as distant effects.

Small diameter nerve fibers are rich in peptide generating capacity as well as conducting information from the body into the central nervous system. Because the unique characteristics of the Pro-Sport II™ signal theoretically result in the activation of these thin nerve fibers, a continuous supply of regulatory peptides is expected.

Packages of programs capable of turning on or modulating whole sets of functions are created. The result is a flowing continuum of information that regulates ongoing functions as well as repairing disturbed functions.

EXPRESSED AND SUPPRESSED PAIN

Concept of Expressed/Suppressed Pain

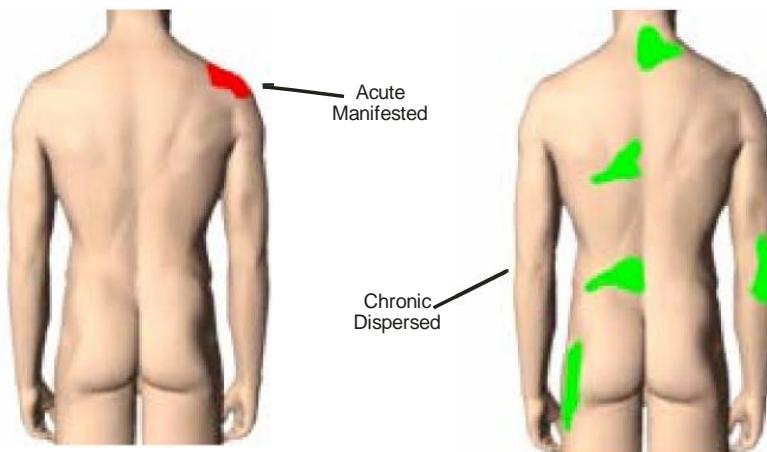
Typically, pain is divided into the two categories of acute and chronic. Acute pain is generally the result of a specific insult or injury and has a well-defined cause. The cause of chronic pain is frequently difficult to isolate and may be the result of numerous overlapping factors. Chronic pain may not always express itself at the same level or in the same pattern. What is a strong pain in a certain situation may only be a dull ache at other times. Such being the case, a third category of pain is added to acute and chronic. This additional category is called aggravated chronic pain and is used when a chronic pain expresses itself with greater focused intensity. This aggravation may occur as a result of an unusual activity or some general stress.

BEST™ devices approach the management of pain by classifying acute pain and aggravated chronic pain in the same class of methodologies. The pronouncement of pain that occurs in the aggravated chronic pain complaint has many similarities to that of the manifest pain associated with an acute complaint. By comparison, sustained chronic pain is typically entwined with other regulatory challenges and is managed using alternative device techniques.

The goal of treatment in acute pain is threefold. Reduce the pain as much as possible, as fast as possible, and limit any possible complications connected to the pain such as muscle tension. The end goal is a full resolution of the acute pain condition. The goal of treatment of aggravated chronic pain is also to reduce the pain as much and fast as possible. The difference however in the treatment of aggravated chronic pain is that when the aggravation has been managed, the treatment planning must now proceed along a more complex course of resolving the deeper roots of the pain condition. It would be expected that once the aggravation has been controlled, a different set of methodologies would be required to finally resolve the chronic complaint.

Differentiating Between Acute Pain and Chronic Exacerbated Pain

Acute pain typically accompanies trauma, injury, or inflammation. Acute pain is the body's signal to the CNS about pathological malfunction or a dangerous state of the cells and tissues.



Acute and Exacerbated Chronic Pain

Chronic pain is developed when the pathological process has not been healed by the body and the body is accommodated to that process. Chronic pain is the consequence of the acute pain, when the

body has not been able to deal with it. When the body experiences any negative effect from the external environment, a chronic long-lasting pathological process is activated; in other words, the body produces an exacerbation of the chronic pain.

Acute Pain (6 to 10)

- Pain — very pronounced, severe, strong
- Exacerbated by touch, pressure or movement
- Preventing normal functioning
- Length -- onset recent, up to one month
- Accompanied — surrounding tissues hot, hyperaemic, swollen (edema)

Exacerbated Chronic Pain (1 to 5)

- Pain — ache, rather dull than strong
- Could be exacerbated by touch, pressure, or movement
- Limited normal functioning
- Length -- onset from one month to years
- Accompanied — surrounding tissues have slightly elevated temperature, pallor, slight swelling (edema)

The 4 Rules or Principles

Pro-Sport II™ therapy has a standard by which to select a technique when attempting to treat pain. If one were to consider the choice of techniques in terms of rules, Rule #1 would have to be to direct treatment towards the point of obvious or greatest pain. If the patient can point to the pain then that specific location is used as a fundamental reference in the treatment methodology. If one cannot isolate the pain or the pain is not sufficiently pronounced at the time of the session then another method strategy is used instead.

Rule No. 1 – Clear all scar tissue at 77.93 Hz

Because scar tissue can have such a devastating effect on the rest of the body, we suggest that all scar tissue, apparent or not, be cleared. EAV tests on similar technology indicate that the device has the potential of neutralizing energy build-up on the scar itself.

Pain Treatment Protocols

Albert Fleckenstein at Freiburg University in West Germany (co-discoverer of the sodium-potassium pump) has shown that once a nerve membrane has lastingly lost its electrical potential of -80 mV and it's lastingly hypo- or hyper-polarized, the ion pumps in the cell membrane cannot work, and the cell is not only electrically paralyzed but also the metabolism of the cell itself cannot work properly. Certain waste products of the cell's metabolism cannot be eliminated from the interior of the cell, and toxic waste accumulates inside the cell. This toxic waste is responsible for the perpetuation of the abnormal membrane potential.



A local disturbance of the autonomic nervous system can affect the autonomic nervous system as a whole, leading to sometimes severe dysfunction at sites remote from the scar tissue responsible for the disturbance.

Rule No. 2 - Treat Local Point of Pain (POP)

Rule #2 or the Point of Pain Rule is used when the pain is expressed in a clear way. This would apply regardless of whether it is an acute pain or an aggravation of a chronic pain. At times the pain simply cries out even if the patient is sitting or standing quietly without any movement at all. This is certainly the most obvious condition of expressed pain and easily calls for the Point of Pain Rule and its related techniques. There will also be patients who report multiple locations of pain. In such a case if they can easily distinguish the strongest or dominant point of pain, then once again Point of Pain Rule can be used.

It is possible that the pain complaint may not be obvious when sitting or standing quietly but can be easily evoked by making a movement such as turning the head or lifting the arm. In such a case, the pain is really not hidden because it can express itself as a result of a simple movement or shifting the posture. If the pain expresses itself as a result of a simple movement, then it would still elicit the Point of Pain Rule.

Rule No. 3 – Treat the General Zone-Hidden Pain Protocol



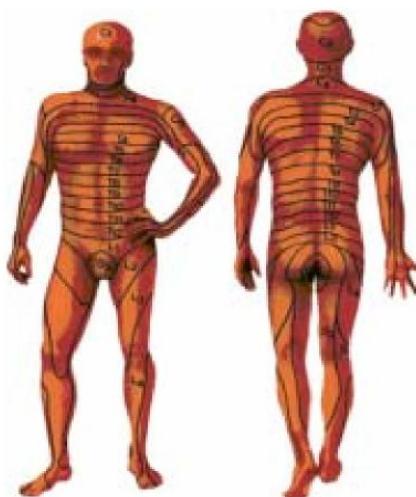
There are certainly times when pain is not expressing itself clearly even with the efforts of simple movements. It definitely was hurting earlier but at the time of the appointment, the pain seems to have somehow disappeared. It is as though it were hiding. In this condition, Pro-Sport II™ therapy considers the pain as being temporarily suppressed by the body's own actions. The pain complaint still exists but is temporarily unwilling or unable to clearly express itself. This pain suppression should not be mistaken as pain resolution because it is fully capable of quickly and fully expressing itself again. In the case of this type of temporary suppressed pain, Pro-Sport II™ therapy moves to the third rule known as the Hidden Pain Rule for its selection of techniques. If the pain is hidden at the time of the treatment, then one would follow Rule #3. Rule #3 is extremely helpful in the search for the best areas to treat when the pain does not clearly express itself.

Rule No. 4 – Treat the Horizontal

When the point of pain protocol is not fully effective in resolving a pain syndrome, the para-vertebral area at the level of the spine horizontally corresponding to the focal point of the pain can be treated. A dermatome is the horizontal zone that circumscribes the body and corresponds to an area of skin that is supplied by a single pair of dorsal sensory nerve roots associated with the vertebrae of that zone.

Treat the para-spinal (para-vertebral) nerve root by placing the device about 1-1.5 inches adjacent to the spinal midline, on the same side of the spine as the general area of pain. The device should be placed at the same level on the para-spinal area that horizontally corresponds to the pain area. By treating the corresponding, horizontal, para-spinal area, one will observe a direct effect in the general area of pain. Typically full resolution of the pain syndrome is realized by the patient toward the end of the para-spinal treatment.

Other techniques that are effective in utilizing *Horizontal* treatment are derived from Rule #4.



Segmental Organization

The body is organized in a number of segments that in the simplest way resemble the many floors in a high rise office building. Conventionally, these segments are seen as arising according to the nerve roots that emerge along the length of the spinal column. In the skin, this organization is represented in the dermatomes.

It is well known that all of the related structures within a segment are served by the same nerve root and maintain a sensitive relationship with each other. For example, a muscle can easily be tense and painful because the associated organ is experiencing stress while the related dermatome is displaying altered sympathetic activities. Pro-Sport II™ therapy has techniques that interface with these segmental activities.

Dermatomes and Horizontals

In Pro-Sport II™ therapy, a simple pattern of rings or bands on the skin's surface is utilized to interface with the segments. These reflex bands are called horizontals and have a strong similarity to dermatome patterns. These simple horizontals are sections that are thought to emerge in the very earliest stages of ovum organization. In a way, the horizontals could be thought of as primitive segments that evolved into place before any complex structures manifested and remain functional even in the matured body.

The techniques that act upon these horizontals could be considered related to Rule #4. Rule #4 is the Horizontal Rule and is used to expand the pain management techniques of the Point of Pain Rule and the Hidden Pain Rule. Work in the horizontals is very important to insure the full resolution of acute pain.

INTRODUCTION TO “BIOFEEDBACK” MODE

Initial Reaction, Ongoing Reaction, Dose, Zero

Having explored the Biofeedback features of the Pro-Sport II™ device, we will now begin to look at the second main category of the device known as its evaluation mode.

Biofeedback mode uses numbers to help guide practitioners through various treatment processes. The Biofeedback mode is an excellent complement to the subjective or treatment techniques. One is not better than the other. They are simply two different ways to achieve the same result. Both approaches use the exact same BEST™ process. With subjective modes you track the body's reaction through various signs and reactions. In Biofeedback you use numbers to help you know how the body is responding. Expert device practitioners use both subjective and treatment modes and Biofeedback modes at various times. Let's have a look at the screen as it appears in Biofeedback.

- Start by turning the device **ON** by using the small slider switch at the side of the device. After the basic introduction, you will see a screen showing the default **Relax Assess** setting. Press the grey center button once, Relax Assess Selected will appear.

Press the  button and you will see **Biofeedback** highlighted on the screen.

- Applying the device electrodes to the skin, the screen will begin to display the initial reaction and the initial coefficient. On the left-hand bottom row there is a digital read-out of the results, showing the three changing values of **Ongoing reaction: coefficients: velocity**.

When the device electrodes are on the skin, numbers will be displayed on the screen, which reflect the body's reaction to the stimuli in real time. Please see the next examples.

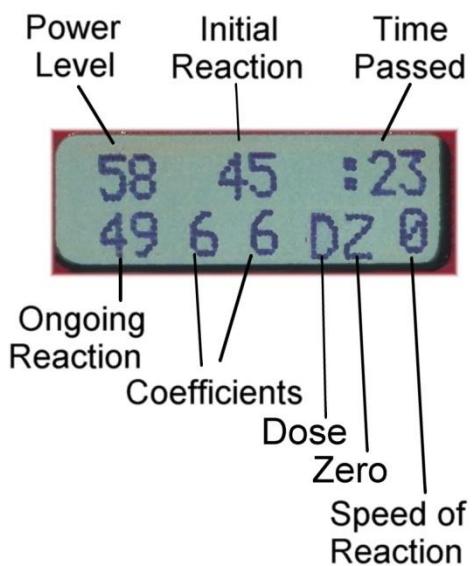


67 (Power) :01
Relax Assess

67 (Power) :03
Biofeedback

67 (Power) 30 (IR) :03
33 15 16 1

Biofeedback Mode Display



Referring to Illustration A and B below

- **34** represents the timer
- **67** = the power adjustment comfortable for the client
- **30** represents the Initial Reaction (IR)
- **15** represents the coefficient (ratio of the body's change (x))
- **16** represents the second coefficient of body's change (y)
- **33** represents the Ongoing Reaction (OR)
- **D** represents Dose
- **02** represents the speed of change or (velocity) (Response Rate)
- **0** represents the 0 value once it has been achieved, a Z will appear in the second square



Image A



Image B

Initial Reaction (IR):

The **IR** is a relative measure of the body's initial response to the signal. The value is based on impedance and other rate related characteristics. Generally, a higher IR indicates the area of the focus of the treatment. Because the tissue responds dynamically to the signal, the IR will change somewhat each time you remove and replace the device on the skin.

Dose (D):

Dose is a sign (chirp) to the operator which indicates that the body's response to the stimulation is beginning to enter the functional physiological range (95% correction). Basically, a Dose is the indication that the main aspect of the treatment has been successfully completed.

Response Rate (RR) and Zero (Z):

The RR indicates how fast or slow the body is responding to the device's signals. A higher response rate indicates a more active local process. When the body's response has begun to stabilize, the RR will register a Zero. A Zero indicates that another aspect of the treatment has been completed.

Dose (D) + Zero (Z)

A Dose usually comes first and is followed by a Zero. This Dose/Zero sequence indicates that the body activity has entered the functional physiological range and has stabilized in that range. If the Zero appears before the Dose, this indicates that the body activity has become fixed and is no longer responding dynamically to the device. Set the device to Deep Stim for one minute on the point.

When the phrases higher dose, higher zero, lower dose, and lower zero are used herein below, they reference the Ongoing Reaction (OR) when the dose or zero occurs.

Timer (t):

The Timer indicates how long the device was in skin contact. The longer you wait for the dose (D), the more sluggish the process of interaction is; the faster the dose (D) is achieved, the more active is the interaction.

Coefficients: Initial (X) and Ongoing (Y):

The two coefficients displayed are Initial (X) and Ongoing (Y). These indications are the ratio of change of the body's ongoing response to the treatment. Basically, the coefficients reflect the ratio of dynamic interaction at the treatment site. When coefficient (X) is equal to coefficient (Y), this would indicate higher levels of stress at the work site. The highest indication of stress would be when (X) = 1 and (Y) = 1. (When X = Y, break the tie.) This means that the area needs special attention and should be treated until the tie between (X) and (Y) finally breaks. If X is lower than Y, a low dynamic change indicates that the body may need more treatment at that area. When X is greater than Y the dynamic change indicates that the body is approaching satisfactory response to the stimulation.

Now that we have looked at each of the biofeedback values on the screen and developed a fundamental understanding of what they are, we can move to the next step of using these numbers in a practical way. The most frequently used biofeedback number is the Initial Reaction (IR). In general, the higher the IR value, the more significant is that spot. We know if an IR is high or low by comparing it to other related IR values. Basically there is no absolute high value or low value. The value is always a relative one.

Using the Biofeedback Mode

Step 1

Set the device to **Biofeedback** and prepare to look for the highest of the initial reactions (IRs). To make it simple, use your arm as the area on which to search for the IRs.

Step 2

Place the device on the skin outside of the intended area to treat. Press the button (+) to increase the level of power until the patient feels a comfortable pricking sensation.

Step 3

When you place the device on the skin and apply equal pressure, the (IR) Initial Reaction reading will appear. Keep the electrode lengthwise.

Step 4

Take two IR readings at the area you have chosen for this exercise.



Step 5

At the position of the higher IR, place the Pro-Sport II™ device on the area and keep it on the skin until the multi-tone bell rings. This mean you treated to Dose (D).



Example: **IR1 = 34**
 $34 < 33$

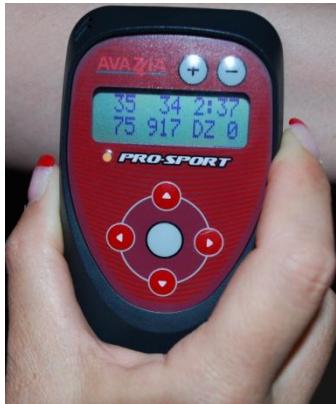
IR2 = 33
 $33 / 50(D)$

Now, choose exactly the same area on the other arm and follow the same principle: take readings of two IRs. Higher readings of IR treat to Dose*.

Example: **IR1 = 27**
 $27 < 31$

IR2 = 31
 $31 / 49^*$

Step 6

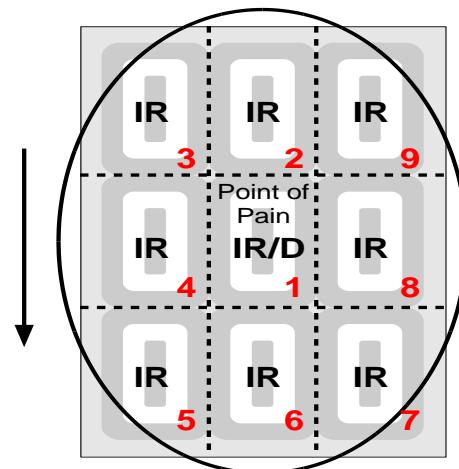


Now compare each arm value of the Dose (D). Treat the higher readings of the Dose(D) to Zero by placing the Pro-Sport II™ device at the position of the highest Dose(D), and wait for the second bell to ring while response rate (the last number in the bottom row) reaches 0 or/and Z appears beside the D.

Instruction to Point of Pain Principle

Step 1

Take an **IR** reading at the point of pain (the center upper number). Remove device from the skin and immediately replace it to get a Dose (D) reading (the lower right of center) portion of the screen. A “**D**” will appear after the X and Y coefficients.



Step 2

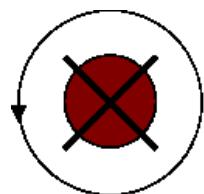
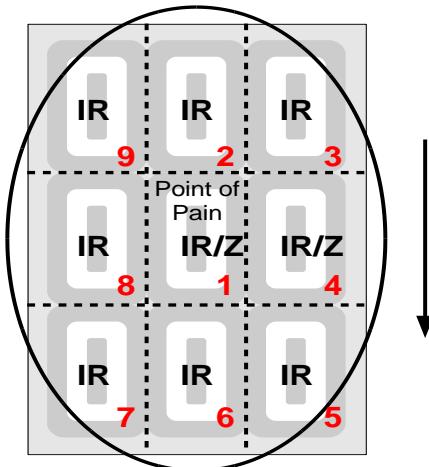
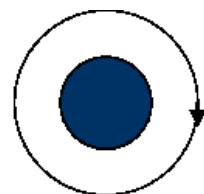
Now, take IR readings at the positions shown above (nine counter-clockwise). Any IR that is higher than the center IR should be taken to Dose. Remember to remove and replace the device to make a Dose.

Step 3

When you have finished treatment at the Point of Pain, repeat the same on the Contra-lateral Position. Apply the same protocol using the mirror reflection position. The exact original Point of Pain location is on the mirror left/right opposite of the patient. That spot is the center of your next set of nines. Because it is a mirror opposite, this time proceed clockwise around the center when taking your IR's instead of counter-clockwise.

Step 4

Now you have two areas to compare: The Point of Pain area and the Contra-lateral Point area. Look at all of the doses from both sides and choose the single highest dose from both areas. Take this one spot to Zero.

The Point of PainThe Contra-lateral point

Example:

33/53D	30/47D	25
28	29/45D	24
24	26	37/ 61D
<i>Point of Pain Side</i>		

41/67D/88	38/61D	32
38/59D	35/52D	28
32	26	24
<i>Contra-lateral Side</i>		

Next we incorporate the central nervous system with the activities in the peripheral. Remove the device from the body and place it on the position of the Zero. Move the device horizontally until you reach the corresponding position at the center of the spine. Now turn the device ON again and take an IR reading. Remove the device and replace it immediately to make a Dose (D).

33/53	30/47	25	X	41/67/88	38/61	32
28	29/45	24		38/59	35/52	28
24	26	37/ 61		32	26	24
<i>Point of Pain Side</i>			<i>Spine</i>	<i>Contra-lateral Side</i>		

IR/D Spinal Process						
33/53	30/47	25	33/48D	41/67/88	38/61	32
28	29/45	24		38/59	35/52	28
24	26	37/ 61		32	26	24
Point of Pain Side			Spine	Contra-lateral Side		

Step 6

If the spinal Dose is higher than the Dose with the Zero (in the Point of Pain or Contra-lateral areas), then make a Zero on the spinal position. If it's not higher then do nothing.

Example A:

33/53	30/47	25	33/48	41/ 67 /88	38/61	32
28	29/45	24		38/59	35/52	28
24	26	37/ 61		32	26	24
Point of Pain Side			Spine	Contra-lateral Side		

Example B:

33/53	30/ 47D	25	33/ 78D /98	41/ 67 D / 88	38/ 61D	32
28	29/ 45D	24		38/ 59D	35/ 52D	28
24	26	37/ 61D		32	26	24
Point of Pain Side			Spine	Contra-lateral Side		

Step 7

If you now have two Zeros, choose the higher Zero and paint the spot in all four directions using either **Stimulate** or **Deep Stimulate** settings of the treatment modes. If you have only one Zero, paint it using **Stimulate** or **Deep Stimulate**.

33/53	30/47	25	33/48	41/67/88	38/61	32
28	29/45	24		38/59	35/52	28
24	26	37/ 61		32	26	24
Point of Pain Side			Spine	Contra-lateral Side		

Step 8

Now we prepare to work along the horizontal that is involved in the pain. You will start working from the site with the highest Zero. (You may have two Zeros to choose from or only one.) The goal is to treat any active site along the horizontal that may be contributing to the pain. You will either be moving towards the spine or away from the spine. Remember the direction of the work is determined by starting at the site of the highest Zero whether it is in the periphery of the body or is central at the spine. Depending on the location of the Point of Pain, the work along the horizontal may be very short or rather long.

For example, if the Point of Pain was at the shoulder blade, the horizontal work could be just six inches from shoulder blade to the spine. If the Point of Pain was on the chest, then the work would include the area from the front of the torso, around the side of the torso to the spine. Lastly if the Point of Pain was at the ankle, then the horizontal work would include the whole length of the leg or maybe even up and down the leg.

33/53	30/47	25	33/48<<<<<	41 /67/88	38/61	32
28	29/45	24		38/59	35/52	28
24	26	37/ 61		32	26	24
Point of Pain Side			Spine	Contra-lateral Side		

When treating the horizontal, use AVAand the default settings. Move firmly and steadily along the horizontal. When/if an active site is located, reset the device to STIMULATE or DEEP STIMULATE and paint in four directions. Once there is a dynamic change (sticky! non-sticky; color red, color white; sound quiet, sound loud; pain, no pain), reset back to your default settings on the same level of power and paint further.

Step 10

Alternatively, you can treat the horizontal by taking readings of IR. Move along the horizontal in the chosen direction and take readings of IR. Any IR that is higher than the IR of your starting point is taken to Dose (D). Remember to remove and replace the device when you make a Dose (D).

Step 11

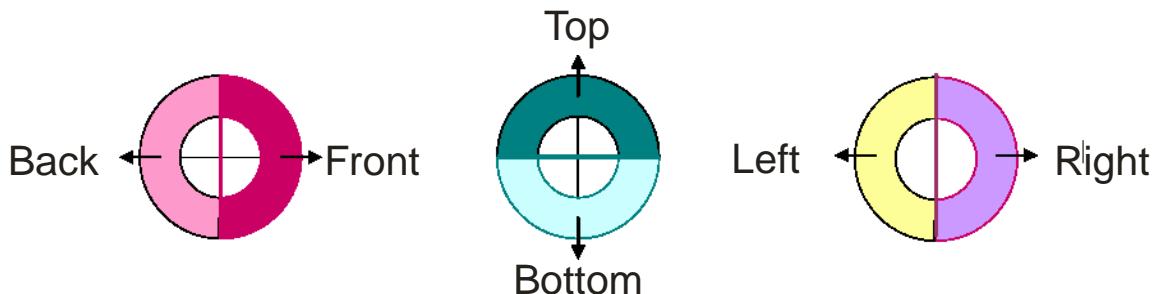
The highest Dose (D) on the horizontal is taken to Zero. The site of the Zero is then painted in four directions using STIMULATE or DEEP STIMULATE.

REFLEX RELATIONSHIPS

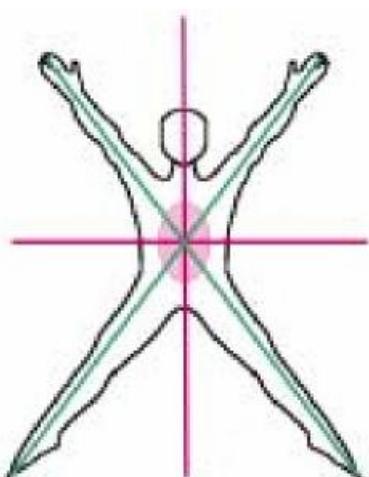
Symmetrical and Reciprocal Organ Projections

Pro-Sport II™ interactive neurofeedback theory recognizes that the internal functions of the body are coordinated through multiple neurological relationships. These neurological relationships are generally reflex in nature, which means that they are involuntary responses and automatic reactions to a stimulus. Normally, these reflexes are instinctive, unconditioned, and unlearned. They are in a sense hardwired into the body and are essentially the same in every person. This network of reflexes is a fundamental requirement for successful self-regulation. The network is organized and expresses itself in a number of predictable patterns and relationships.

Reflex relationships are embedded into the organism at the earliest stages of the development of the embryo. Interestingly, the fundamental relationship of left/right, front/back, and top/bottom are expressed in the very first stages of cellular development of the fertilized ovum. Various versions of symmetry are some of the first facets of organization to appear in the early shaping of the complex human body.



Interactive neurofeedback techniques often utilize these fundamental relationships as a way of increasing the degree of benefit in the therapy. One of the most frequently used reflex relationships is the basic mirror symmetry of left and right. Clinical experience has confirmed that incorporating the mirror opposite symmetrical area in the treatment of a complaint yields higher levels of success. For example, a complaint in the left knee may often diminish when treatment also includes the right knee. Even more surprising is the fact that at times, just the sole treatment of the right knee successfully reduces the pain in the left knee.



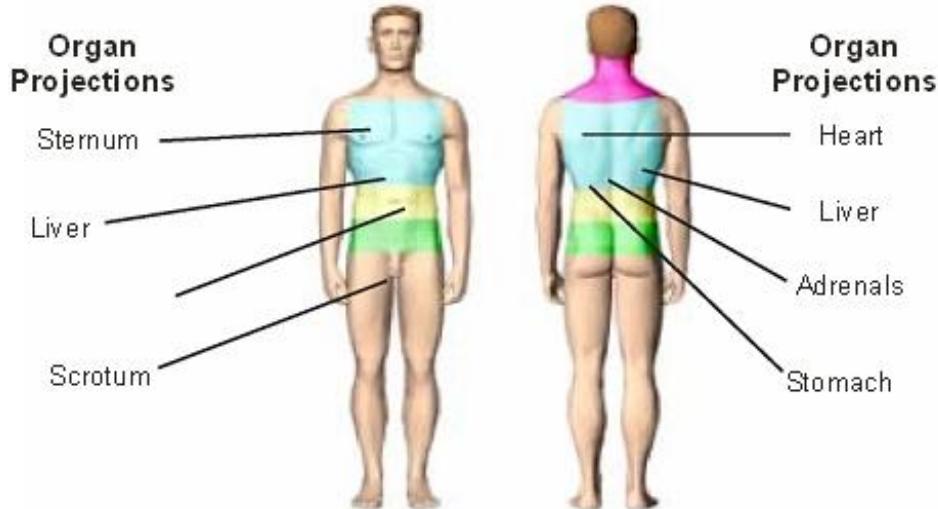
Other than the obvious left/right mirror relationship, the front/back and top/bottom relationships are frequently used to improve upon the effects of a basic treatment protocol. With a small creative step, it is easy to begin seeing even more potential reflex patterns. Diagonal and oblique reflex relationship emerges in the developing body hierarchy useful in treatment protocols. An example of a simple diagonal reflex relationship is the left shoulder and the right hip.

This pattern includes the basic left/right mirror correspondence combined with the top/bottom relationship and connects them on a diagonal. This reflex organization becomes quite logical when you consider the primitive neurological motor actions of the cross-crawl reflex and the upright walking reflex with its opposite arm/leg actions.

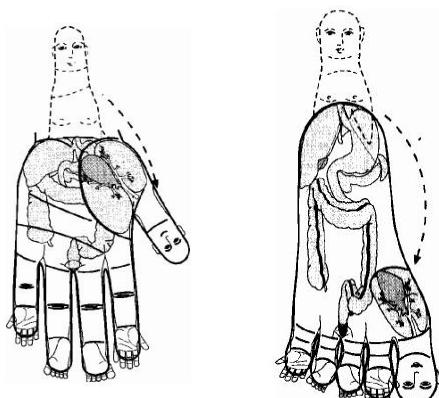
Lastly, an oblique reflex relationship includes three-dimensional correspondence: pain in the left elbow at the back part of the joint could be treated on the right knee at the front.

In a sense, you could consider these reflex relationships as hard-wired circuits in the body. Although the actual structures and pathways remain obscure, it is probable that these reflex patterns are a result of the coordination of activities in the central nervous system.

Another category of reflex expression is found in the Organ Projections which are predictable areas on the skin associated with specific internal organs. These Organ Projections remain standard from person to person and do not vary over time. If the organ is functioning properly, the skin characteristics remain neutral. If the organ is experiencing some degree of dysfunction, the skin in the area of the Organ Projection is altered. One could say that when the Organ Projection in the skin is altered by the organ dysfunction, the Organ Projection has now become active. The stimulation of an active Organ Projection acts to re-enforce self-regulation and reduce pain associated with the organ.



Reflex Organ Projections are often but not always located in the skin over or near the related organ. Some organs have projections on both the front and back of the torso. There are also projections that exist at some distance from the organ and may even express themselves on the limbs.



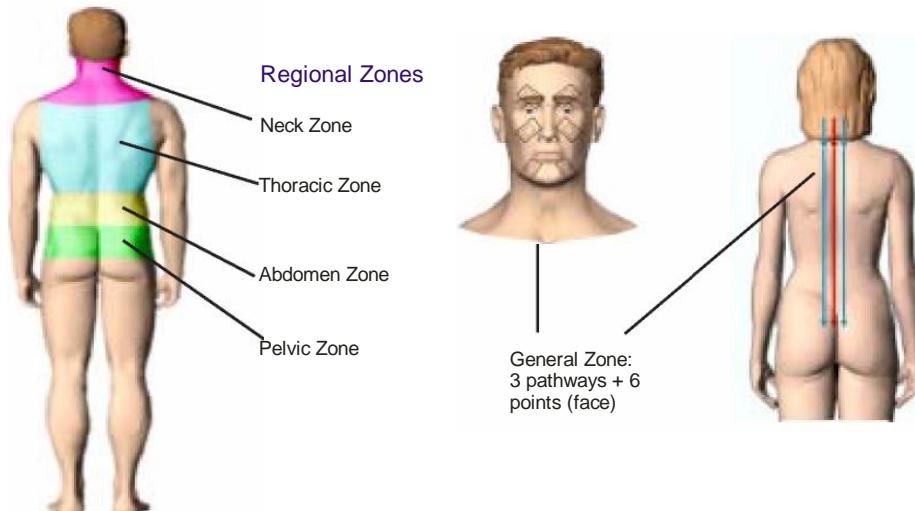
Special micro-reflex projections occur on the hands and feet. These micro systems are well known in certain Oriental reflex-based therapies and are useful in augmenting basic biofeedback electro stimulation techniques that are often used in BEST™ protocols. Such a micro reflex system even exists on the surface of the face as well as the ears.

There are also zones that reflect regional activities that are not limited to one specific organ. These regional expressions are known as the General Zone, the Regional Zones, and the Target Zones and are used often in BEST™ protocols.

The General Zone is the Spinal Zone and is the most extensively used reflex zone and covers a large area on the back along the spine and the face. This large zone is very helpful and effective because it permits access to processes of the central and peripheral nervous systems associated with all of the primary internal organs.

The Regional Zones include the Abdomen Zone, the Neck Zone, the Thoracic Zone, and the Pelvic Zone.

Lastly, there are the Target Zones, which occur throughout the body and have relationships to common types of pain.



PAIN TAPPING TECHNIQUE

Clinical experience has resulted in a number of recommended clinical protocols that utilize various combinations of reflex expressions in the skin. Pain conditions can sometimes be well managed using Reflex Projection Zones like:

- Organ Projections both local and distal
- Micro-Reflex Projections
- Mirror, Diagonal or 3-D Diagonal Correspondences
- Target Zones
- Regional Zones
- General Zone

Considering the use of a clinical protocol in certain cases that have a clear pre-existing diagnosis may serve as a useful shortcut in session planning.

Pain Tapping Technique

There is more than one approach to working in **Biofeedback** mode when a person is able to localize or point to the location of pain. This alternate approach is especially effective when someone has a very specific pain related to a recent trauma such as a fractured rib or sprained ankle. In this case when the trauma is very fresh and the pain highly localized, you can use this simple Pain Tapping technique instead of the more elaborate Point of Pain technique.

Step 1

Circle the point of pain chosen by patient. Then take readings of IR REPEATEDLY in Biofeedback mode and note the highest IR reading. Keep taking IR readings until you get two IRs lower than the highest IR reading.

Example: 34, 37, 45, 55, 57, **63**, 59, 55

Step 2

Now repeat the same process on the exact same spot but take it to Dose. Take the Dose reading REPEATEDLY until you get two Doses lower than the highest Dose reading.

Example: 45*, 62*, 68*, 57*, **84***, 69*, 71*

Step 3

Now set the Pro-Sport II™ device to DEEP STIMULATE mode. Set the power at higher level so that it is a bit uncomfortable but still acceptable. Paint the pain area in all four directions.

If the patient cannot determine the point of pain, you can expand that area of treatment by treating all nine positions the same as Step 1 and Step 2.

PAIN RING TECHNIQUE

Introduction to the Pain Ring Technique

The Pain Ring technique is a supportive **secondary** technique used to extend or reinforce the effects of other primary techniques. It may be used relative to any localized pain especially if the pain is a secondary expression that emerges as a result of some other primary technique. The Pain Ring technique may also be applied briefly and generally over a band that was just treated using the more specific Horizontal technique. It is also a good complement to the Pain Tapping technique used in acute trauma conditions.

The Pain Ring technique is only done in the **Acute** mode. Remember that the Horizontal technique is looking for Active Sites and the Pain Ring technique is not. The device may be held and moved in any angle just as long as the stroking is methodical and complete. The Pain Ring always circles the body 360 degrees. It starts at the painful spot, via the spine, keeps going and finally returns to the same painful spot again. This stimulation around the body combined with the local point of pain reinforces the positive effects of the Pro-Sport II™ treatment.

Pain Ring Technique with Single Device

1. Set the device to the Acute mode and power up using the + button until the energy from the device feels stronger than the pain itself.
2. Place the device on the point of pain.
3. Stay at the point for 30 seconds and then slowly start moving towards the spinal column.
4. Once you have reached the center of the spinal column stop and stay for 30 seconds.
5. Then move further along the horizontal until you reach the point of pain again.
6. Stay at the point again for 30 seconds.

Pain Ring Technique with Two Devices

1. Place the first device at the point of pain.
2. Place the second device at the horizontally corresponding position on the spinal column. Stay at the points without moving for 30 seconds.
3. Slowly start moving the device, which is on the point of pain towards the spinal column.
4. At the same time, with the second device, which is on the spinal column, slowly move towards the point of pain.
5. You should reach last stops (spinal column and the point of pain) simultaneously. You can repeat this technique few times.

Pain Ring Technique with Point of Pain Technique

After a localized pain has been treated using the Point of Pain technique, the treatment is continued along the corresponding horizontal level of the spinal segment. This work is from the highest Zero and the lower value. Additionally, you may also apply the Pain Ring technique after the specific Horizontal technique.

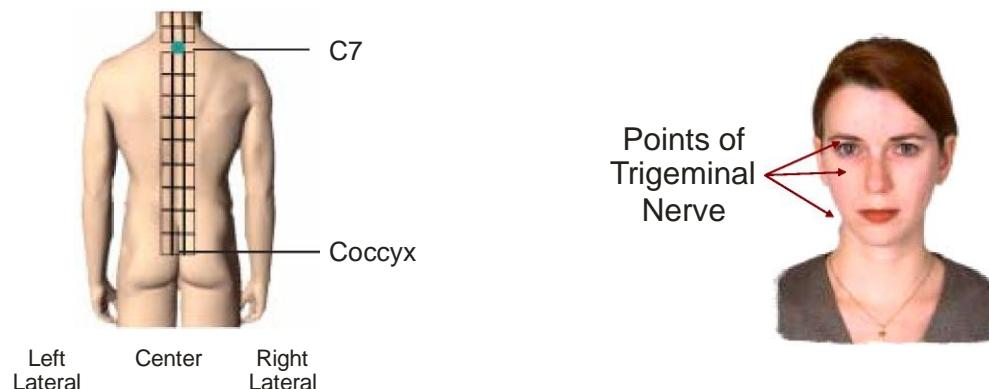
The Pain Ring begins at the highest Zero, progresses entirely around the body, and returns finally to the spot with the highest Zero. In this way, the Pain Ring technique combined with the Point of Pain and Horizontal techniques will reinforce the positive effects of the treatment.

Hidden Pain Technique

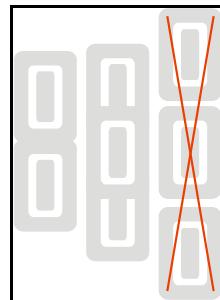
So far we have studied ways of working with a person that has manifest or expressed pain at the time of the session. Both the Point of Pain technique and the Pain Tapping technique are used when a person can localize the pain by pointing with one finger. However there are also times when a person with a pain complaint arrives for a session but without any actual pain expressing at that particular time. There are also times when the person does have pain at the time of the session but it is diffuse or vague, and they are truly unable to localize it.

Such cases often present themselves as part of a sub acute or even chronic condition. In cases when the pain is not obvious, we use an approach called the Hidden Pain technique. The Hidden Pain technique is used when the pain is more suppressed than expressed.

Hidden Pain technique is applied to area of complex reflex relationships called General Spinal Zone. The Spinal Zone includes three pathways on the back and six points on the face.

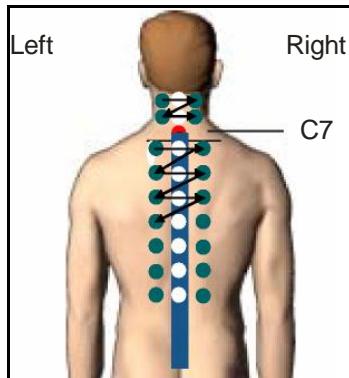


The central route starts from below C7 on the back and goes down the spinal column (right on the spinal processes) to the tip of the coccyx and finishes on the neck. When working on the neck, go from the hairline down to C7. Usually there is only room for one electrode length.

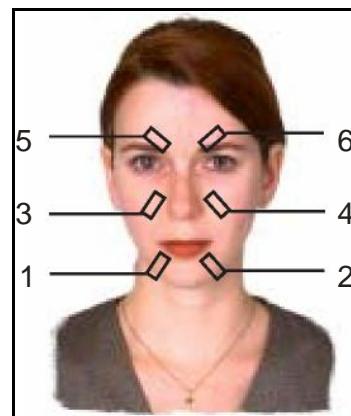


The electrode should be placed overlapping or abutted.

When working around the spinal column, place the device centrally right on the spinal processes and on each side laterally next to the central position.



The second route is the left and right para-spinal pathways, respectively. Always start from the left and go to the right. As on the central route, go from below C7 to the coccyx and then onto the neck.



The Spinal Zone also includes six points on the face. The sites used are the exit points of the trigeminal nerve from the skull. Start from your left to the right (relative to the therapist).

Now that we have the basic patterns for the Hidden Pain technique, let's explore the actual method of application. Start by positioning the patient in an upright seated posture with their back exposed from neck to tailbone.

Hidden Pain Protocol

Step 1

Place the electrode vertically on the spine itself just below C7 and take an IR reading. Immediately take IR readings on the left para-spinal site and then the right para-spinal site at the exact same level of the spine.

Step 2

Compare the three IRs (spinal, left, and right) and make a Dose on the highest IR site.

Step 3

Proceed down the length of the back in the same way, taking IR readings at each level, comparing the three IRs, and making a Dose on the highest IR site.

<u>Gauche</u>	<u>Centre</u>	<u>Droit</u>
23	21	29/49*
31/43*	25	26
29	35/52*	29
34/59*	21	29
31	33/66*	22
26	29	33/48*
24	25	29/51*
27	21	37/62*
30/53*	25	26
26	20	27/54*
21/41*	19	18

Step 4

Having finished at the coccyx area, proceed up to the neck area and apply the same center-left-right protocol. Depending on the length of the neck or the location of the hairline, you may be able to do one or two levels on the neck.

<u>Left</u>	<u>Center</u>	<u>Right</u>
42	29	49/67*
33	34/53*	26

Step 5

Now that the back and neck are completed, find the highest Dose on the central spine route and the highest on the left and the highest on the right para-spinal routes. You must have at least two IRs to make a comparison. Make a Zero on the highest Dose in each route. If there is only one Dose or no Dose along a route, then leave it and do nothing more there.

Left	Center	Right
42	29	49/67*/81
33	34/53*	26
23	21	29/49*
31/43	25	26
29	35/52*	29
34/59* (92) SW	21	29
31	33/66* (89)	22
26	29	33/48*
24	25	29/51*
27	21	37/62*
30/53*	25	26
26	20	27/54*
21/41*	19	18

Step 6

Now if you have more than one Zero, choose the highest Zero. If you have only one Zero, then just choose it. Set your device to **Stimulate** or **Deep Stimulate** setting. Paint the highest Zero site in all four directions.

Left	Center	Right
42	29	49/67*/81
33	34/53*	26
23	21	29/49*
31/43	25	26
29	35/52*	29
34/59*/82	21	29
31	33/66*/89	22
26	29	33/48*
24	25	29/51*
27	21	37/62*
30/53*	25	26
26	20	27/54*
21/41*	19	18

Step 7

Having finished the back and neck completely, now move to the six points on the face. Start from the bottom left position on the face, take readings of IRs, and compare left and right. The higher IR of left and right is taken to a Dose.

Example: Left

39/48*
29
21

Right

35
45/57*
29/42

**Step 8**

Now with all six face points finished, compare the Doses of the bottom, middle and top points on the left and then on the right. If there are two or more Doses on one side, take the highest Dose to Zero. If that face Zero is higher than the highest Zero on the back and neck, set your device to Stimulate or Deep Stimulate settings and paint the site in all four directions.

Example: Left

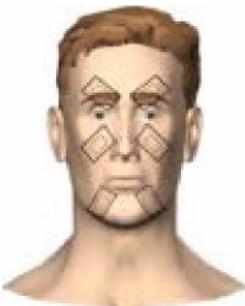
39/48*
29
21

Right

35
45/57*89
29/42



Another Example:	<u>Left</u>	<u>Right</u>
	39/48*	35
	29	45/67*/107/Deep Stim
	21	29/42**


Step 9

Make a note of the horizontal level on which your highest Zero (and **Stimulate** or **Deep Stimulate** painting) took place. This will help you in your further treatment planning. This horizontal will be especially important if your patient's pain complaint is located in this same horizontal. The Horizontal technique may be applied in this same session if time permits or in a following session. The Horizontal technique may be applied using either Acute mode painting or Biofeedback mode measurements.

When treating the horizontal using Acute mode, set Pro-Sport II™ device in default setting, start at site of Deep Stimulate treatment moving slowly, firmly, and steadily along the horizontal. If the Deep Stimulate mode site is on the torso then work around the body until you reach the midline at front of the body. If the Deep Stimulate mode site is on the face, then work from the center of the face to the hairline/ear. When/if an Active Site is located, reset device to Stimulate mode or Deep Stimulate mode and paint in four directions. Once there is a dynamic change, reset device to your default settings on same level of power and paint further along horizontal (dynamic change = sticky => nonsticky; color red => color white; sound quiet => sound loud; pain => no pain).

Alternatively, you can treat the horizontal by taking readings of IR in Biofeedback mode. Move along the horizontal in chosen direction and take readings of IR and search for significant sites. End the work when you reach the midline on the front of the torso or hairline/ear on the face. Any IR that is higher than the IR of the Deep Stimulation mode site, which is your starting point, is taken to Dose. The highest Dose on the horizontal is taken to Zero. The site of the Zero is then painted in four direction using Stimulate or Deep Stimulate modes.

Another example (option):

<u>Left</u>	<u>Center</u>	<u>Right</u>		
23	32/52*/66°	24		
24	21	28/34*	43/61*/87°	21
23	26/45*	25		
35/43*	23	33	23	27/39*
34/37*	25	26		
39	36	43/51*	32/41 *	29
44/45*	32	35		
34	37/47*	25		
47/58/92°	42	18		
22	27	32/59*/102°/SW		

Hidden Pain Pattern Analysis

The work done in the Spinal Zone using the Hidden Pain technique not only creates a positive therapeutic effect at the time of application but also offers the practitioner important information on how to proceed in deepening the process and planning of the next session. The body proceeds along the path of pain resolution in stages that are frequently predictable but also sometimes surprising. In some ways it can be likened to the unwinding of a knot.

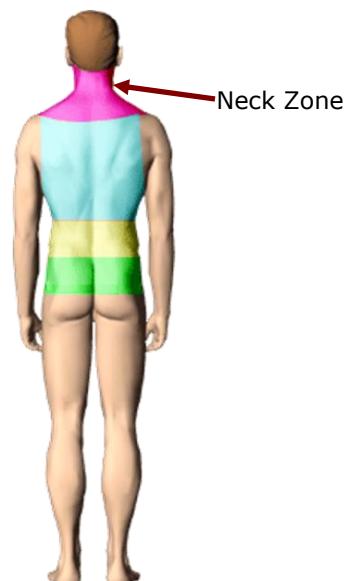
The Hidden Pain technique yields many measurements offering insight into the areas and levels of the body that are active in the problem solving related to the pain condition. By correlating the significant active sites determined by the Hidden Pain technique with the pattern of reflex organization in the body, the practitioner can be lead to exactly the next steps in helping resolve the pain condition at a deeper level. Acute conditions are prevented from shifting into chronic conditions, and the exacerbated chronic condition can be shifted into an expression that would facilitate therapy resulting in a full and final resolution. Basically the goal is to achieve maximum effect in minimum time.

The Hidden Pain technique results in the application of **Stimulate** (or **Deep Stimulate** if you choose it instead of Stimulate mode) at a specific location somewhere within the Spinal Zone. That specific location gives the practitioner a very reliable clue as to where the body is active in its attempts to resolve its problem. If the Stimulate (or Deep Stimulate) treatment is somewhere on the central route of the Spinal Zone, then a particular new Regional Zone is indicated for treatment in the next session. If the Stimulate or Deep Stimulate treatment is located somewhere along the para-spinal routes or facial route, then treatment along the related horizontal becomes an excellent choice and may be applied immediately in that same session if time permits or used as the main focus of the next session (assuming the next session does not elicit Rule #2).

Hidden Pain Analysis - Step by Step

Step 1 -- Central Spinal Route

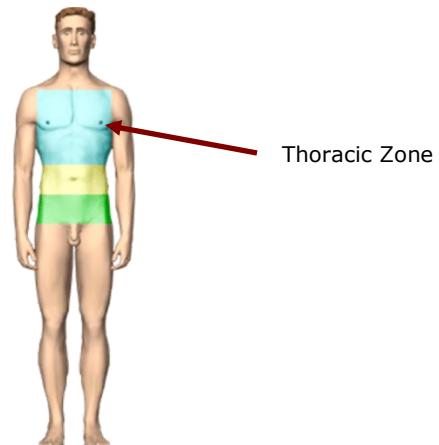
First we'll examine the activity that focuses on the central route. The central route is divided into sections each of which relate to a specific Regional Zone. The following diagrams will illustrate which area of the central route relates to which Regional Zone.



Step 3

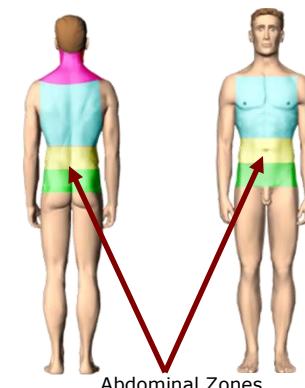
Thoracic Zone

Left	Center	Right
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X

**Step 4**

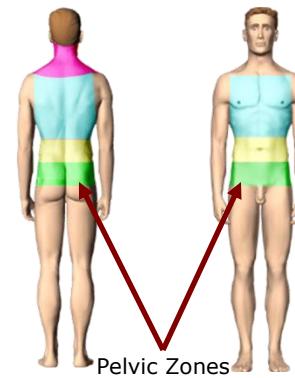
Abdominal Zone

Left	Center	Right
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X

**Step 5**

Pelvic Zone

Left	Center	Right
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X

**Step 6-- Para-spinal Routes**

Now we will examine the results when activity focuses along either of the para-spinal routes on the back.

Step 7

Right Neck
Horizontal

Left	Center	Right
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X

Step 8

Left Upper and
Right Lower Arm
Horizontals

Left	Center	Right
X	X	X
XX	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X

Step 9

Left Interrupted
(Breast)
Horizontal

Left	Center	Right
X	X	X
X	X	X
X	X	X
XX	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X

Step 10

Right Trunk
Horizontals

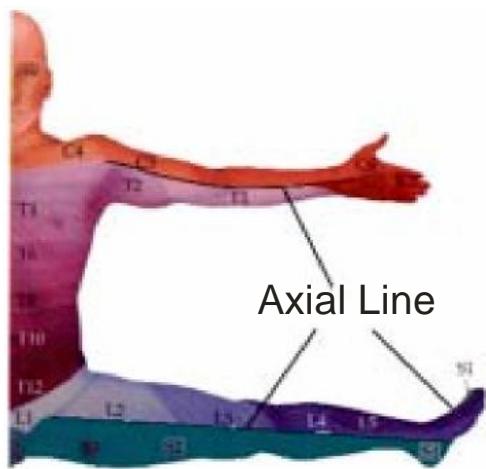
Left	Center	Right
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X

Step 11

Left Upper and
Right Lower Leg
Horizontals

Left	Center	Right
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
X	X	X
XX	X	X
X	X	X

When reviewing the horizontals on the neck and torso, we find that there are basically three types: short, long, and interrupted. The short wrap around the axis of the body, the long include the appendages, and the interrupted is at the level of the armpits.

**Short**

- Neck
- Chest
- Abdomen

Long

- Upper arm
- Lower arm
- Upper leg
- Lower leg

Interrupted

Third position

Step 12 -- Face Points

Because the Spinal Zone also includes work on the six points of the face, it is possible to extend the analysis into the various measurements on the face. The face has a complex topography that alters the patterns of the horizontals in specific ways. As before, if the Stimulate mode (or Deep Stimulate) activity focuses on one of the face points, work along the corresponding facial horizontal.

Step 13 -- Head Horizontals

Head horizontals are mainly on the face. If the head is bald or shaved, the horizontal continues wherever skin is available. In serious cases, a comb electrode may be used on the scalp.

Step 14 -- Chin Horizontal

Whenever Active Site is detected within a chin horizontal, treat the Neck Zone as well.

Step 15 -- Nose Horizontal

Whenever Active Site is detected within the nose horizontal, treat the Abdomen Zone as well.

Step 16 -- Forehead Horizontal

Whenever Active Site is detected within the forehead horizontal, treat the Pelvic Zone as well.

TREATMENT PLANNING

General Treatment Guidelines

If possible, ask the patient not to shower or bath for two hours before and after the treatment. It may be necessary to shave or closely trim body hair in the treatment area, as the device requires electrical contact with the skin. The comb electrode may be a happier option.

It is best to treat on a treatment table in a comfortably warm room, with the patient either sitting or lying down.

Before you start the treatment

- Take a history of the patient's complaints—past and present.
 - Note any medication being used. (Note that if the patient is on a strong opiate, antidepressant, or steroid medication, it may reduce the effectiveness of the outcome from the treatment. Do not cancel any medication; always refer to the doctor.)
 - Note any allergies, family history, etc.
 - PAIN “here and now”

Questioning and assessment

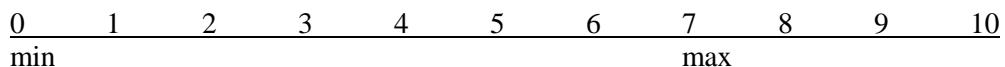
Ask the patient to point with one finger (if possible) to where the most pressing pain is **right now**. Determine the dominant point of pain location: top/bottom of body? Front/back of body? Left/right of body?

Ask the patient to recall anything about the pain, for example: character, severity, timing, radiation etc. Is there a movement that triggers or regenerates the pain?

If possible, make the patient elicit/demonstrate the pain. Where appropriate compare with the opposite side. Test any weaknesses. If necessary, reinforce the pain.

Assess muscular tone: hyper/hypo tone; note any atrophy.

Check active and passive range of movements and record **before** and **after** the treatment. Assess and record the pain score **before** and **after** the treatment:



Basic Review--Where and how to treat

- If the patient has a localized pain, apply the Pro-Sport II™ device locally using the principles of Rule #2 and the Point of Pain technique.
 - If the patient has many pain complaints or none at present, treat the General Spinal Zones using the principles of Rule #3 with the Hidden Pain technique and Rule #4 with the Horizontal technique. Following use of the Hidden Pain technique in General Spinal Zone, it may also be possible to determine what Regional Zone or horizontal in which to focus your work in the next session.
 - In order to increase benefits of the treatment, when working locally also work on the symmetrical or mirror areas. Keep in mind that other diagonal and oblique reflex relationships may also be helpful. If it is not possible to work on pain areas because of open wounds, plaster or bandages, you should work on mirror, diagonal, or oblique reflex zones. The co-lateral mirror reflex is the most commonly used.

Frequency of treatments

Acute pain

Treat every day, even as frequently as three/four times a day (with a break between each session not less than two hours).

Chronic pain

Every other day.

Optimum length of application

Optimum recommended time for a session is 30 minutes. Occasionally, you may provide shorter or longer sessions that correspond to a special set of needs.

Number of sessions in a course of treatment

- Typically: 7–14 sessions in case of acute pain syndrome.
- Typically: 14–21 sessions in case of chronic pain syndrome.
- Plan breaks between series of sessions. In case of chronic pain syndrome, the break from treatment course should be considered when the patient shows substantial improvement from pain, even though not fully resolved. The break is an essential part of the biofeedback electro stimulation therapy as it prevents accommodation to the treatment.
- The next course of treatments should be started when the patient experiences a new pain or an exacerbation of the old pain. It is preferred, if possible, that treatment not be resumed sooner than two weeks time.

HOME USE THERAPIES FOR JOINT PAIN



The Donald and Betty Wolfe Foundation

Dedicated to the Non-Pharmaceutical Relief of Pain

BEST™ Technical Brief Volume 1 No.3

August 4, 2009

Caveat: Cervical pain is a complex issue. This technical brief is intended for educational purposes only and not meant for use as medical advice or for diagnosis. Acute, severe, cervical pain, especially from trauma, may indicate a true medical emergency and require the immediate attention of a qualified health professional. While most cases of cervical pain originate with the musculo-skeletal and/or neurological system, some may be the result of neoplastic (cancer) growth, anursym, infection, localized inflammation, or other causes. One who may present with acute or constant cervical neck pain is urged to immediately consult their physician.

Cervical Neck Pain

Cervical neck pain can arise from a simple or complex cause; and may originate from a single point source or from multiple point sources. Pain may be discriminant, sharp, and focal in nature or indiscriminant, layered, diffuse, and generalized across a broad area. Pain also may be associated with specific movement such as twisting or bending. Cervical pain in this brief will be classified by cause as arising from acute trauma and by chronic degenerative changes.

Pain From Degenerative Disease Process

Aging and Vertebral Instability

As one ages, collagen and elastin in the longitudinal structural fibers comprising ligaments and tendons, cross link due to oxidative damage (aging phenomenon). The result is gradual weakening of the structural integrity of ligaments that knit the vertebrae together into a flexible and strong spine. Micro-fissures and stretching of collateral ligaments result from aging. The vertebral articulations become more lax and instability develops. Often vertebrae become misaligned, termed subluxation, and can cause pain due to compression of nerves. Muscles often spasm in the area surrounding the subluxation. Chiropractic care attempts to relieve subluxation by manipulative therapeutic intervention. Often spinal instability leads to intervertebral disc degeneration or facet joint deterioration due to uneven redistribution of the gravitational forces over areas of the joint that are not capable of prolonged weight bearing. Cartilage is damaged leading to osteo-arthritis (OA).

The Bowling Ball Syndrome

The average human head is approximately the weight of a bowling ball, hence the name of this clinical phenomenon. The sphenoid bone acts like a keystone in a stone masonry arch to anchor and stabilize the other bones compromising the skull. If one observes two pencils--one held horizontally in each ear, many times a disparity of several centimeters between the planes of the pencils is evident. This occurs because of malalignment of the sphenoid bone of the skull. When the sphenoid bone is displaced, the body compensates for the difference by rebalancing the weight of the head in an unnatural way. This is done unconsciously by the balancing mechanism of the body. The redistribution of the center of gravity of the head causes a serious malalignment of the spine. This can shift undue weight to one side and cause wear and tear on the joint

articulations of the affected side of the spine, damaging the joints. Bowling Ball Syndrome is discussed in detail in a separate brief. Bowling Ball syndrome can often be an underlying base cause of complications leading to cervical pain such as osteo-arthritis (OA) and disc degeneration.

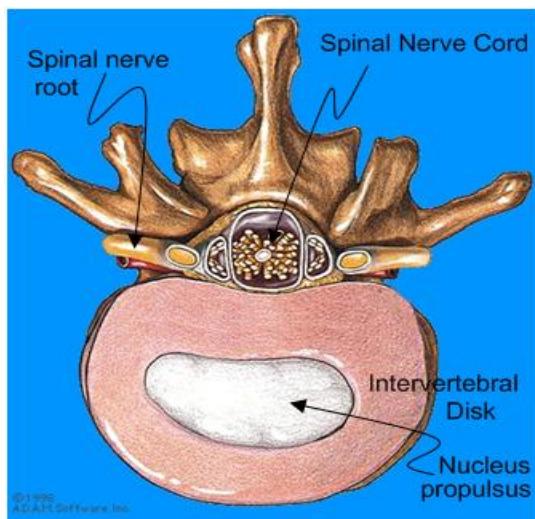
Arthritis

Vertebral joints are susceptible to various forms of arthritis. Arthritis associated with infection within the joint capsule is termed septic arthritis, is an acute condition, and is caused by pathogenic microorganisms. Chronic low-grade infection of the bone is termed chronic osteomyelitis (OM). It may cause swelling and deformity leading to weakness and poor articulation of vertebral joints. Chronic OM may be associated with advanced aging.

Rheumatoid arthritis (RA) is an auto-immune disorder where one's own antibodies attack and destroy cartilage necessary for smooth, gliding, articulation of the joint. Rheumatoid arthritis involves cyclic crippling inflammatory episodes of joints. The cervical and upper thoracic spine can be acutely affected by RA, leading to severe inflammation, pain, and cervical/thoracic spinal deformities such as scoliosis (deviated laterally from the vertical plane), kyphosis (hunch back), lordosis (swayed inward).

The most common form of arthritis is osteo-arthritis where cartilage has degenerated and bone grinds against bone. This form of arthritis occurs when the blood capillary bed underlying the cartilage degenerates due to age related diseases such as vascular disease and chronic inflammation related diabetes mellitus. The cartilage no longer sustains itself metabolically and slowly atrophies. Osteo-arthritis obviously more severely affects the functionality of weight bearing joints such as the hip, knee, and ankle, as well as the spine due to pressure of contact between articulating surfaces. Due to inflammation from damage, the lubricating, normally viscous synovial fluid degrades in consistency and fails to protect the cartilage, leading to more damage and inflammation, descending into a vicious spiral of degeneration. This can be a very painful sequela.

Disc Degeneration

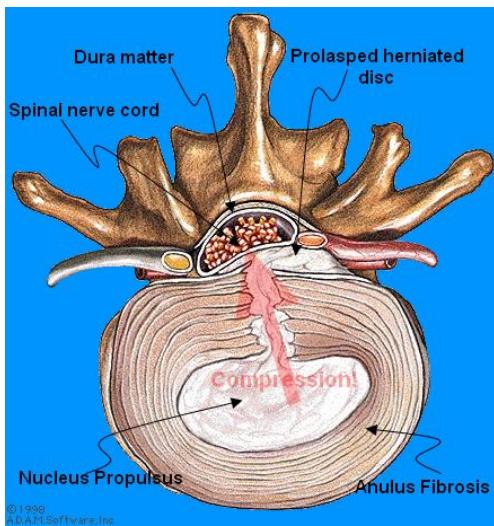


Vertebrae are cushioned by small oval pads of cartilage or disks consisting of a tough outer layer, the annulus, and a soft inner layer, the nucleus.

The diagram at the left displays an anatomically normal cross-sectional view of a spinal vertebra.

The disc is contained in the large circle of bone and acts as a pad to cushion the weight of the body and provide flexibility for the spine by facilitating multiple articulations. The nerve cord containing multiple nerve tracts is protected by encasement in a boney canal. The boney wings on the top and side provide points of insertion for muscles and ligaments. The vertebrae knit together with collateral ligaments on the side and layers of ligaments and muscles associated with the lateral and dorsal processes.

vertebrae knit together with collateral ligaments on the side and layers of ligaments and muscles associated with the lateral and dorsal processes.



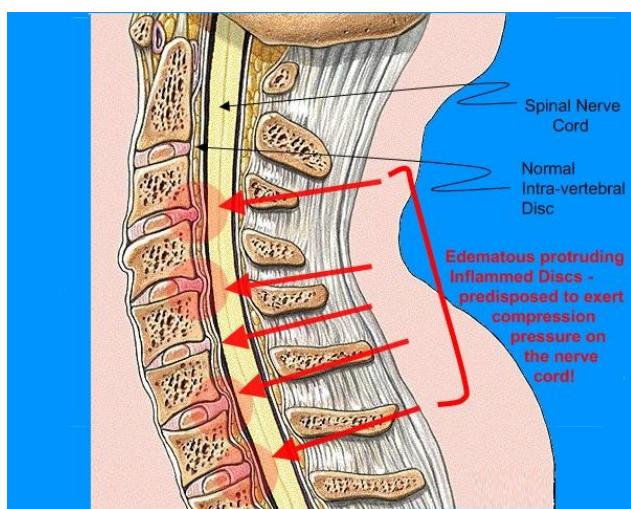
When a herniated cervical disk occurs, a small portion of the nucleus pushes out through a tear in the annulus into the spinal canal. This can irritate a nerve and result in pain, numbness, or weakness in the neck, back, as well as the arm.

The disc in the diagram displays a herniated intra-vertebral disc. The contents of the disc, the disc nucleus pulposus, have prolapsed out a hole in the annulus and entered the space between the bone and the dura matter surrounding the cord, causing severe compression of the composite nerve tracts against the opposite wall of the boney canal. Compression can be an acutely painful condition. Many times the disc does not rupture, but will bulge and compress the nerve.

Diagnosis

Disc problems and orthopedic problems of the spine are diagnosed with imaging technology such as CAT scan or MRI. Associated neurological function deficits are assessed by physical/neurological examination, image scanning, and electro-diagnostic testing.

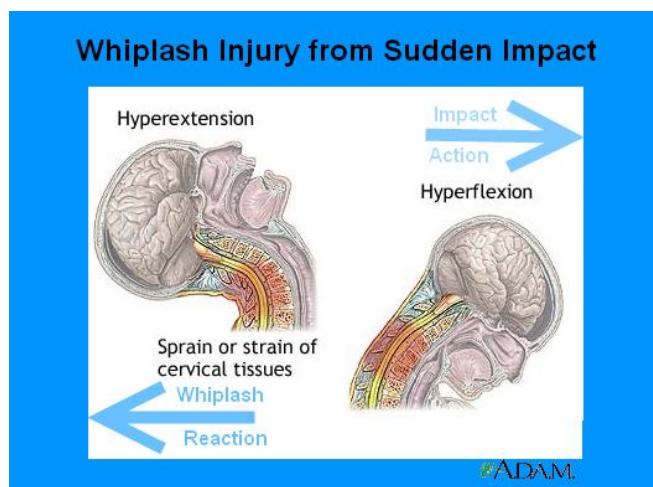
The diagram at the right displays the stages of vertebral degeneration. As discs age or with unusual wear or strain, tears and thinning of the disc wall occurs. The weak or thin area of the disc begins to bulge, placing increasing pressure on the spinal nerve cord. Finally, the disc herniates and ruptures with the contents exuding from the disc into the space between the disc and the dura matter surrounding the cord and compressing the cord's nerve tracts against the opposite wall of the boney canal.



As bone grinds against bone, osteoarthritis develops. This is extremely painful. Osteophytic growths bridge the joint causing fusion/alkalosis, pain, and a loss of flexibility of the spine.

This diagram shows bulging discs throughout the cervical spine, causing inflammation and pain and threatening imminent herniation of intra-vertebral discs. Undue stress or physical exertion could cause severe acute pain or slow throbbing, long-term pain. Osteoporosis or bone degeneration can lead to demineralization and collapse, again leading to severe intractable pain.

Pain Due to Cervical Trauma



The most common condition causing trauma induced cervical pain is muscle strain, muscle pulls, and soft tissue damage due to hyperextension or hyperflexion. Contact sports such as football and wrestling are major contributors to this type of injury. Rear end automobile accidents involving whiplash are extreme examples of these types of strains and many times involve severe contusions and fractures. When there is a sudden uncontrolled and many times unanticipated movement of the head usually in a forward direction, the

sudden stop results in cervical hyperextension and the recoil results in a cervical hyperflexion, hence whiplash-like action.

Blunt trauma may result in bruising and fracture leading to scar and callous formation. Stress and strain or other neck pain may arise due to muscular tightness in both the neck and upper back. Or pinching of the nerves and entrapment syndromes such as carpal tunnel and thoracic outlet nerve entrapment may radiate or refer pain to the cervical region. Prolonged abnormal postures or sleeping positions may induce spasms and pain.

BEST Techniques for Cervical Neck Pain

Technique 1 - Painting

A preliminary exercise is to relax the shoulder by “painting” down the lateral side and front and back shoulder areas. As the electrode head is dragged in a downward gliding motion over the skin surface, friction will dramatically increase over inflamed or painful skin surface areas. These areas should be stroked with a downward motion frequently until smooth gliding is established.

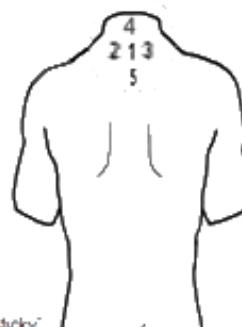
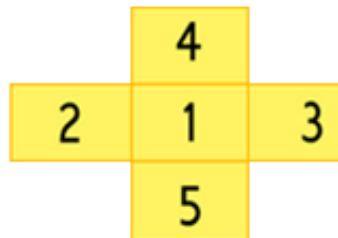
“Painting”	Downward strokes about 6 inches in length	Cervical Area Protocol
<p>Painting refers to the technique of placing BEST device on an area of the skin (shoulder) and then moving it downward in repeated overlapping adjacent strokes of about six inches (14 cm) in length rather like the way we paint a wall, always moving the BEST device in the same downward direction along the skin. More painting may be required in areas of stickiness until the friction subsides and the device glides freely.</p> 		<p>Paint with gliding downward strokes Paint out “sticky” spots Use 1-2-3 method on areas of high electrode coupling with skin surface.</p>

Technique 2 - ABC 1-2-3 Method

Treat the neck area where exceptional drag is noted. These sticky areas should be treated on *Relax* mode by placing the signal delivery head on the skin until the “chirping” sound signals completion of the delivery of a “dose” of micro-current. Then move the signal delivery head to position 2 and repeat the procedure. After the area is covered, switch to *Stimulate* or *Deep Stimulate* mode and paint lightly over the entire area.

ABC - 123

- A Apply the BEST™ Device in relax mode to the point of desired application until it chirps. That area is designated “Area 1”. Then apply the BEST™ Device to Area 2, then move on to area 3, and then area 4, and finally to 5.



- B Similarly apply to related locations

- C “Paint” out “sticky” spots until they are no longer “sticky”

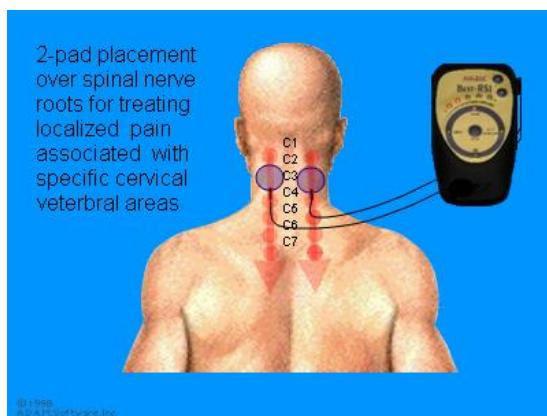
Stimulate for a minimum of two minutes where indicated

Technique 3 - Y Electrode



A “Y”-Electrode is an accessory many physical therapists, massage therapists and chiropractors use to “unlock” muscle masses that are in a state of spasm due to pain. Gentle pressure can be applied using the handle and two ball signal delivery heads. The ball shape allows for better adaptation to the contours of the curved area and the in-folding of facial planes between muscle bellies. The device rapidly shortens preparation necessary for adjustments and deep massage techniques.

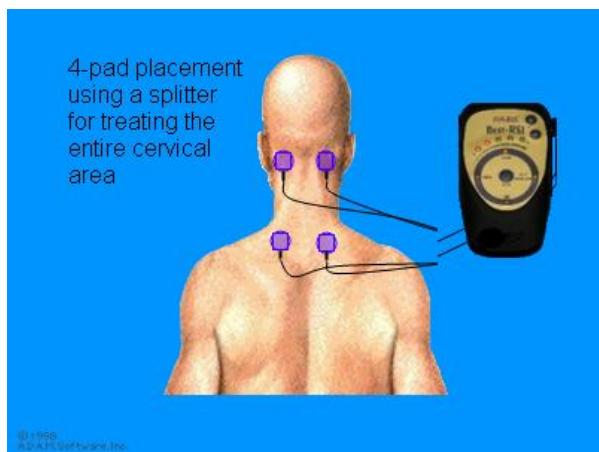
Technique 4 Signal Delivery with Pads



After manual application, therapy may be further augmented by use of pads or other signal delivery appliances.

Apply the self-adhesive pads firmly to the skin surface at the level of the spine where the most intense sensation of pain is present. This area should also be evident from previous application of gliding the electrode head over the skin and perceiving areas of increased friction (i.e. electro-magnetic coupling) between the skin surface and the device.

Technique 5 Signal Delivery with Splitter and 4 Pads



This technique is useful for covering a large surface area where diffuse, indiscriminate point-source pain is present, or multiple vertebral articulations are involved in the pain emanations.

Suggested Setting for Various AVAZZIA™ Models

Multiple treatments appear to have a cumulative effect regarding effectiveness of pain abatement. Average relief from pain, based upon intensity of pain, has duration of 6-8 hours. Individual experience of pain sensation varies greatly, and the period of pain abatement may be less or more, depending upon the conditions presented.

Treatments using any model should be given a minimum of twice per day.

The insert instructions that accompany your device should be read thoroughly before initiating therapy. Consult your physician or caregiver before using this device, and follow his/her instructions carefully.

MODEL	SETTING	DURATION
BEST RSI	Acute	If the neck injury is sustained within the first 48-72 hours - apply directly onto the focus of pain for 20-30 minutes. Substitute this mode instead of <i>Stimulate</i> . Use <i>Acute</i> mode for the first two applications, then <i>RSI</i> thereafter.
	Relax	Find “sticky” spots and use 1-2-3 method to paint out the “sticky spots” covering entire neck and upper back as indicated in users guide
	RSI	20 minutes with pads
	Stimulate	Lightly paint the neck area for several minutes when finished

MODEL	SETTING	DURATION
BEST MED	Relax	Find “sticky” spots and use 1-2-3 method to paint out the “sticky” spots covering entire neck and upper back as indicated in users guide.
	Cycle Stimulate	20 minutes with pads Lightly paint the area for several minutes when finished
MED SPORT	Acute	If the neck injury is sustained within the first 48-72 hours - apply directly onto the focus of pain for 20-30 minutes. Substitute this mode instead of <i>Stimulate</i> . Use <i>Acute</i> mode for the first two applications then <i>Stimulate</i> thereafter.
	Stimulate	Find “sticky” spots and use 1-2-3 method to paint out the “sticky” spots covering entire neck area and upper back as indicated in users guide.
	Stimulate	20 minutes with pads Lightly paint the neck area for several minutes when finished Massage mode may be also used instead of stimulate

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AVAZZIA RSI™ is FDA cleared for the symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-traumatic pain.

This brief is for educational purposes only, and not meant for claiming cure, treatment, and diagnosis or dispensing of medical advice for the condition of cervical neck pain or related conditions. Treatment and medical advice may be obtained by consulting a licensed physician.

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The Donald and Betty Wolfe Foundation

Dedicated to the Non-Pharmaceutical Relief of Pain

BEST Technical Brief Volume 1 No. 2

June 6, 2009

Lumbago (Chronic Lower Back Pain)

Lumbago (also referred to generally as **Low back pain**) is a common symptom of musculoskeletal disorders or of disorders involving the lumbar vertebrae related soft tissue structures such as muscles, ligaments, nerves and intervertebral discs. The condition can be acute, sub acute, or chronic in its clinical presentation. In a small proportion of individuals suffering with acute or sub acute lumbago, the condition can become chronic. The chronic form is often, but not exclusively, related to changes in the vertebral ligaments, binding the spine, leading to joint laxity from aging.

An acute lower back injury may be caused by a traumatic event, like a car accident or a fall. It occurs suddenly and its victims will usually be able to pinpoint exactly when it happened. In acute cases, the structures damaged will more than likely be soft tissue. With a serious accident, osteoporosis, or other causes of weakened vertebral bones, vertebral fractures in the lumbar spine may also occur. At the lowest end of the spine, some patients may have tailbone pain. Others may have pain from their sacroiliac joint at the bottom of the lumbar spine, called sacroiliac joint dysfunction. Sciatica also termed chronic radiculopathy occurs when the sciatic nerve or other nerves contributing to the pelvic plexus that innervates the legs, become pinched. The misalignment of the lumbar vertebra places pressure on the nerves, and the resulting impingement generates pain in the leg and lower back. (*See [Sciatica Technical Brief](#)*)

Lower back pain can be complex in its etiology. Physical causes may include: intervertebral disc degeneration, disc herniation, osteoarthritis, rheumatoid arthritis, a fracture, radiculopathy (nerve root inflammation), or rarely, tumor or acute or chronic osteomyelitis (infection).

Effective therapy may require multiple treatment modalities. Physical therapy and a consistent exercise program including stretching and strengthening the lower back and abdominal muscles are important for all victims suffering from chronic low back pain. BEST™ therapy is an important part of a total treatment and rehabilitation program by alleviating pain and improving the range of motion of extension and flexion.

Lower back pain affects most adults at some stage in their life and accounts for more sick leave and disability than any other single medical condition.

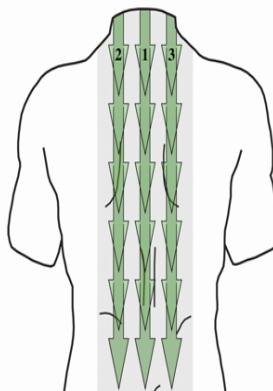
BEST™ Protocol for Lower Back Pain

Technique 1--Painting

A preliminary exercise is to relax the back by “painting” down the midline of the spine and about 2 inches laterally on both sides of the midline. As the electrode head is dragged in a downward gliding motion over the skin surface, friction will dramatically increase over inflamed or painful skin surface areas. These areas should be stroked with a downward motion frequently until smooth gliding is established.

“Painting”

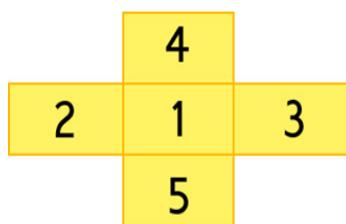
“Painting” refers to the technique of placing the BEST™ Device on an area of the skin and then moving it downward in repeated, overlapping, adjacent strokes of about six inches (15cm) in length, rather like the way we paint a wall, always moving the BEST™ Device in the same direction along the skin. More painting may be required in areas of “stickiness” until friction subsides and the device glides across the surface of the skin easily.



Technique 2--ABC Method

ABC - 123

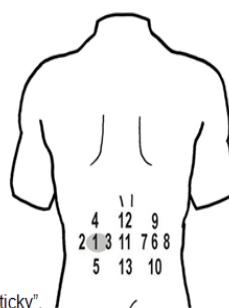
- Apply the BEST™ Device in relax mode to the point of desired application until it chirps. That area is designated “Area 1.” Then apply the BEST™ Device to Area 2, then move on to area 3, and then area 4, and finally to 5.



- Similarly apply to related locations.

- “Paint” out “sticky” spots until they are no longer “sticky”.

Stimulate for a minimum of two minutes where indicated.



Treat the lower back area where exceptional drag is noted. These sticky areas should be treated on *Relax* mode by placing the signal delivery head on the skin until the “chirping” sound signals completion of the delivery of a “dose” of micro-current. Then move the signal delivery head to position 2 and repeat the procedure. After the area is covered switch to *Stimulate* or *Deep Stimulate* mode and paint lightly over the entire area.

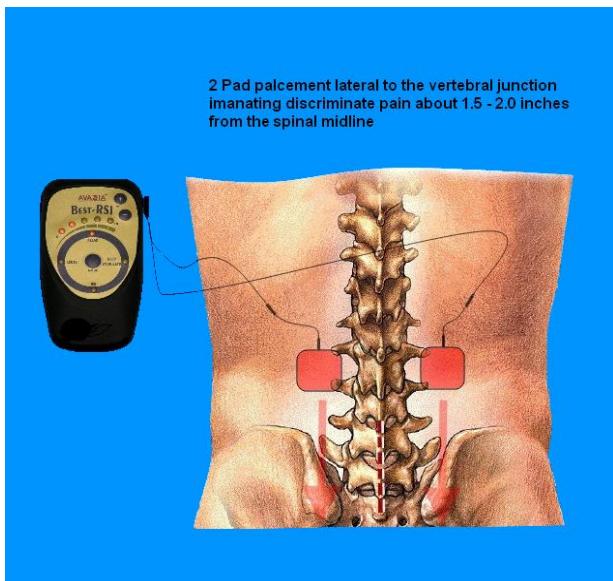
Technique 3--Signal Delivery with Y-Electrode

A “Y”-Electrode is an accessory many physical therapists, massage therapists and chiropractors use to “unlock” muscle masses that are in a state of spasm due to pain. Gentle pressure can be applied using the handle and two ball signal delivery heads. The ball shape allows for better adaptation to the contours of the curved area and the in-folding of facial planes between muscle bellies. The device rapidly shortens preparation necessary for adjustments and deep massage techniques.

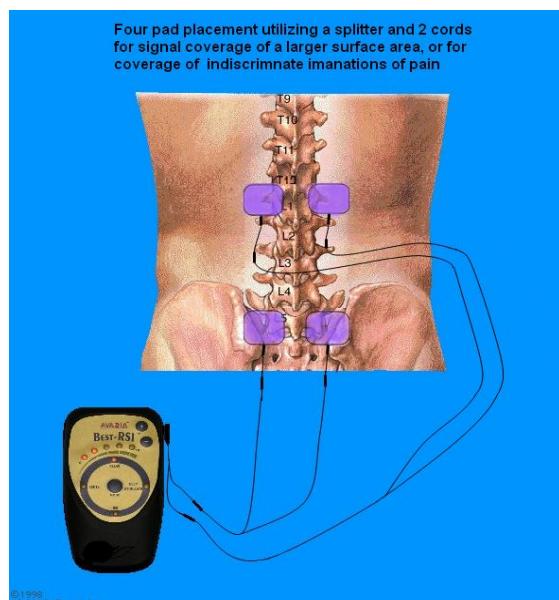


Y-Electrode for applying pressure to muscle masses and facial planes

Technique 4--Signal Delivery with Pads



After manual application, therapy may be further augmented by use of pads or other signal delivery appliances. Apply the self-adhesive pads firmly to the skin surface at the level of the spine where the most intense sensation of pain is present. This area should also be evident from previous application of gliding the electrode head over the skin and perceiving areas of increased friction (i.e. electro-magnetic bounding) between the skin surface and the device. The pads should be 1.5-2.0 inches from the dorsal midline of the spine, placing them over the root area for maximum stimulation.



Technique 5--Signal Delivery with a Splitter, an Additional Cord, and 4 Pads

This technique is useful for covering a large surface area where diffuse, indiscriminate point-source pain is present, or multiple vertebral articulations are involved in the pain emanations.

Suggested Setting for Various AVAZZIA™ Models

Multiple treatments appear to have a cumulative effect regarding effectiveness of pain abatement. Average relief from pain, based upon intensity of pain, has duration of 6-8 hours. Individual experience of pain sensation varies greatly, and the period of pain abatement may be less or more, depending upon the conditions presented.

Treatments using any model should be given a minimum of twice per day.

The AVAZZIA™ QUICK GUIDE and insert instructions that accompany your device should be read thoroughly before initiating therapy. Consult your physician or caregiver before using this device and follow his/her instructions carefully.

MODEL	SETTING	DURATION
BEST RSI	Acute	If injury is sustained within the first 48-72 hours - apply directly onto the focus of pain for 20-30 minutes. Substitute this mode instead of <i>Stimulate</i> . Use <i>Acute</i> mode for the first two applications, then <i>RSI</i> thereafter.
	Relax	Find “sticky” spots and use 1-2-3 method to paint out the “stickys” covering entire foot and lower leg as indicated in users guide
	RSI	20 minutes with pads
	Stimulate	Lightly paint the area for several minutes when finished
BEST MED	Relax	Find “sticky” spots and use 1-2-3 method to paint out the “stickys” covering entire foot and lower leg as indicated in users guide
	Cycle	20 minutes with pads
	Stimulate	Lightly paint the area for several minutes when finished
MED SPORT	Acute	If injury is sustained within the first 48-72 hours - apply directly onto the focus of pain for 20-30 minutes. Substitute this mode instead of <i>Stimulate</i> . Use <i>Acute</i> mode for the first two applications the <i>Stimulate</i> thereafter.
	Stimulate	Find “sticky” spots and use 1-2-3 method to paint out the “stickys” covering entire foot and lower leg as indicated in users guide
	Stimulate	20 minutes with pads
	Stimulate	Lightly paint the area for several minutes when finished Massage mode may be also used or instead of stimulate

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AVAZZIA RSI™ is FDA cleared for the symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-traumatic pain.

This brief is for educational purposes only, and not meant for claiming cure, treatment, diagnosis, or dispensing of medical advice for the condition of plantar fasciitis. Treatment and medical advice may be obtained by consulting a licensed Podiatric Physician

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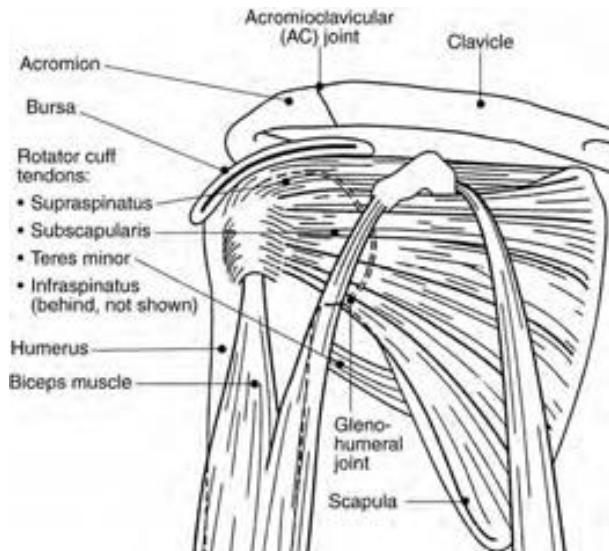
The Donald and Betty Wolfe Foundation

Dedicated to the Non-Pharmaceutical Relief of Pain

BEST Technical Brief Volume 1 No. 2

July 28, 2009

Pain related to Bursitis and Shoulder Injuries



The shoulder joint is a complex structure whose integrity is dependent upon ligaments, tendons, and bursas for strength and function. The shoulder is held tightly to the thorax by muscles and connective tissue forming a type of sling. The shoulder is not tightly knit by collateral ligaments as other types of joints. The structural design allows for greater range of motion and direction, but at the cost of reduced robustness with regard to wear and tear.

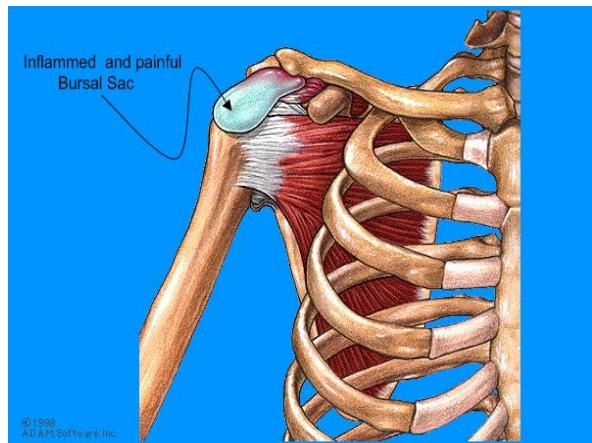
All joints are susceptible to various forms of arthritis. Arthritis associated with infection is termed septic arthritis and is caused by pathogenic microorganisms.

Rheumatoid arthritis is an autoimmune disorder where antibodies attack and destroy cartilage necessary for smooth gliding articulation of the joint. Rheumatoid arthritis involves cyclic inflammatory episodes that is crippling. The most common form of arthritis is osteo-arthritis where cartilage has degenerated and bone grinds against bone. This form of arthritis occurs when the blood capillary bed underlying the cartilage degenerates because of age-related diseases. The cartilage no longer can sustain itself metabolically and slowly atrophies. Osteo-arthritis obviously more severely affects the functionality of weight bearing joints such as the hip, knee, and ankle, as well as the back, due to pressure and contact between articulating surfaces.

The bursa of the shoulder consists of a sac-like structure filled with synovial fluid. The bursa functions as lubrication and cushioning for the tendon which it surrounds and allows the tendon to smoothly glide up and down.

The bursa can become irritated and chronically inflamed leading to the painful condition known as bursitis.

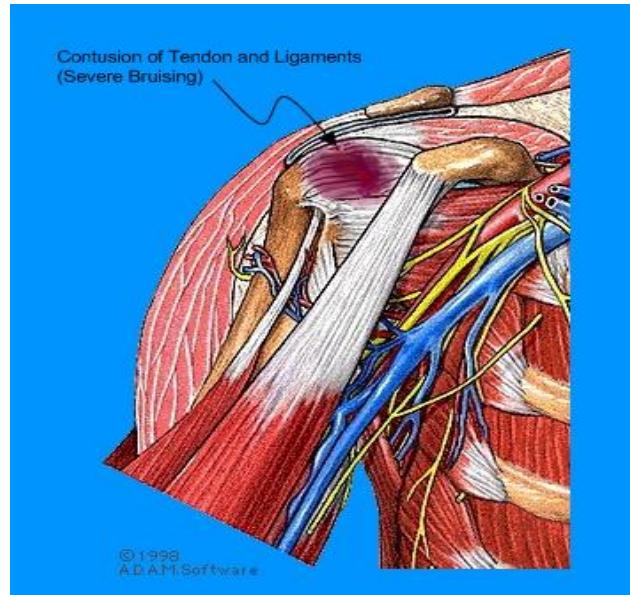
Another common condition associated with athletic injuries, falls, and overuse is contusion of the tendons and ligaments surrounding the shoulder joint. The protrusion that the shoulder offers makes this injury quite common.



Contusions to the ligaments and tendons can occur from overextension injury to the joint, excessive strain to the shoulder, blunt trauma, and repetitive strain injury common to meat packers, laborers, football players, and tennis players. When bone is also bruised, these injuries can be very painful, especially as the arm is rotated.

Shoulder injuries can be slow healing due to reduced blood supply available for tissue repair.

Another common injury associated with age-related weakening of connective tissue, but also common with over exertion and repetitive strain injury is rotator cuff tears. The torn joint capsule is repaired surgically, and lengthy and extensive physical therapy is required for functional rehabilitation. Pain and weakness is present when specific arcs of motion extend above the plane of the shoulder.



Treating Pain Related to the Shoulder with BEST Devices

Effective therapy may require multiple treatment modalities. Physical therapy and a consistent exercise program including stretching and strengthening the shoulder and upper back and neck muscles are important for those suffering from shoulder injuries, bursitis, and injuries. BEST™ therapy is an important part of a total treatment and rehabilitation program by alleviating pain and improving the range of motion of extension and flexion without pain.

Technique 1 - Painting

“Painting”

Painting refers to the technique of placing BEST device on an area of the skin (shoulder) and then moving it downward in repeated overlapping adjacent strokes of about six inches (14 cm) in length rather like the way we paint a wall, always moving the BEST device in the same downward direction along the skin. More painting may be required in areas of stickiness until the friction subsides and the device glides freely.



Shoulder Protocol

Paint with gliding downward strokes

Paint out “sticky” spots

Use 1-2-3 method on areas of high electrode coupling with skin surface

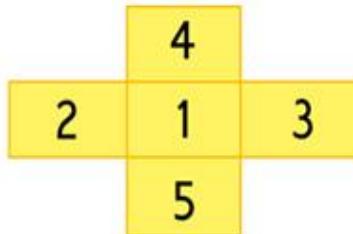
A preliminary exercise is to relax the shoulder by “painting” down the lateral side and front and back shoulder areas. As the electrode head is dragged in a downward gliding motion over the skin surface, friction will dramatically increase over inflamed or painful skin surface areas. These areas should be stroked with a downward motion frequently until smooth gliding is established.

Technique 2 - ABC 1-2-3 Method

Treat the shoulder area where exceptional drag is noted. These sticky areas should be treated on *Relax* mode by placing the signal delivery head on the skin until the “chirping” sound signals completion of the delivery of a “dose” of the unique biofeedback micro-current. Then move the signal delivery head to position 2 and repeat the procedure. After the area is covered switch to *Stimulate* or *Deep Stimulate* mode and paint lightly over the entire area.

ABC - 123

- A. Apply the BEST™ Device in relax mode to the point of desired application until it chirps. That area is designated “Area 1.” Then apply the BEST™ Device to Area 2, then move on to area 3, and then area 4, and finally to 5.



- B. Similarly apply to related locations.

- C. “Paint” out “sticky” spots until they are no longer “sticky”.

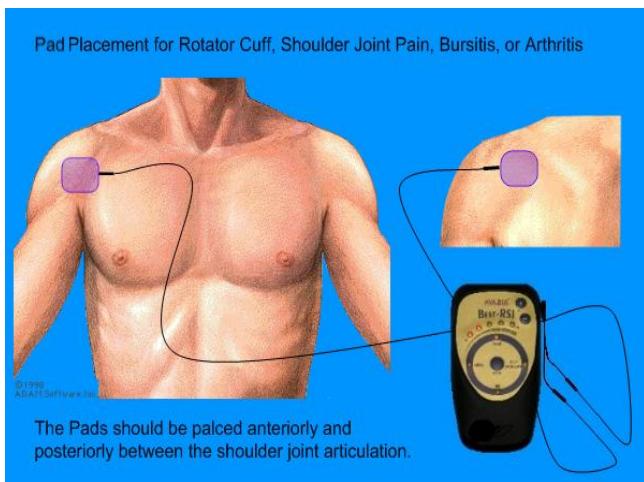
Stimulate for a minimum of two minutes where indicated.

Technique 3 - Signal Delivery with Y-Electrode



A Y-Electrode is an accessory many physical therapists, massage therapists and chiropractors use to “unlock” muscle masses that are in a state of spasm due to pain. Gentle pressure can be applied using the handle and two ball signal delivery heads. The ball shape allows for better adaptation to the contours of the curved area and the in-folding of facial planes between muscle bellies. The device rapidly shortens preparation necessary for adjustments and deep massage techniques

Technique 4 - Signal Delivery with Pads

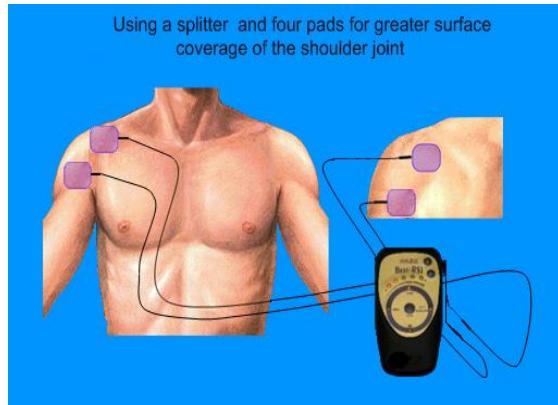


After manual application, therapy may be further augmented by use of pads or other signal delivery appliances.

Apply the self-adhesive pads firmly to the skin surface at the level of the spine where the most intense sensation of pain is present. This area should also be evident from previous application of gliding the electrode head over the skin and perceiving areas of increased friction (i.e. electro-magnetic bounding) between the skin surface and the device.

Technique 5 Signal Delivery with Splitter and 4 Pads

This technique is useful for covering a large surface area where diffuse, indiscriminate point-source pain is present, or multiple vertebral articulation are involved in the pain emanations



Suggested Setting for Various AVAZZIA™ Models

Multiple treatments appear to have a cumulative effect regarding effectiveness of pain abatement. Average relief from pain, based upon intensity of pain, has duration of 6-8 hours. Individual experience of pain sensation varies greatly, and the period of pain abatement may be less or more, depending upon the conditions presented.

Treatments using any model should be given a minimum of twice per day.

The AVAZZIA™ QUICK GUIDE and insert instructions that accompany your device should be read thoroughly before initiating therapy. Consult your physician or caregiver before using this device and follow his/her instructions carefully.

MODEL	SETTING	DURATION
BEST RSI	Acute	If the shoulder injury is sustained within the first 48-72 hours - apply directly onto the focus of pain for 20-30 minutes. Substitute <i>Acute</i> mode instead of <i>Stimulate</i> . Use <i>Acute</i> mode for the first two applications, then <i>RSI</i> thereafter.
	Relax	Find “sticky” spots and use 1-2-3 method to paint out the “sticky” spots covering entire shoulder area as indicated in users guide
	RSI	20 minutes with pads
	Stimulate	Lightly paint the shoulder area for several minutes when finished
BEST MED	Relax	Find “sticky” spots and use 1-2-3 method to paint out the “sticky” spots covering entire shoulder and upper arm and neck as indicated in users guide
	Cycle Stimulate	20 minutes with pads Lightly paint the area for several minutes when finished

MODEL	SETTING	DURATION
MED SPORT	Acute	If the shoulder injury is sustained within the first 48-72 hours - apply directly onto the focus of pain for 20-30 minutes. Substitute this mode instead of <i>Stimulate</i> . Use <i>Acute</i> mode for the first two applications the <i>Stimulate</i> thereafter.
	Stimulate	Find “sticky” spots and use 1-2-3 method to paint out the “sticky” spots covering entire shoulder area as well as upper arm and neck as indicated in users guide
	Stimulate	20 minutes with pads
	Stimulate	Lightly paint the shoulder area for several minutes when finished Massage mode may be also used or instead of stimulate

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AVAZZIA RSI™ is FDA cleared for the symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-traumatic pain.

This brief is for educational purposes only, and not meant for claiming cure, treatment, diagnosis, or dispensing of medical advice for the condition of plantar fasciitis. Treatment and medical advice may be obtained by consulting a licensed Podiatric Physician

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APPENDIX A: ANTI-INFLAMMATORY EFFECTS OF ELECTRONIC SIGNAL TREATMENT

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Focused Review

Anti-inflammatory Effects of Electronic Signal Treatment

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Inflammation often plays a key role in the perpetuation of pain. Chronic inflammatory conditions (e.g. osteoarthritis, immune system dysfunction, micro-circulatory disease, painful neuropathy, and even heart disease) have increased as baby boomers age. Medicine's current anti-inflammatory choices are NSAIDs and steroids; the value in promoting cure and side effect risks of these medications are unclear and controversial, especially considering individual patient variations.

Electricity has continuously been a powerful tool in medicine for thousands of years. All medical professionals are, to some degree, aware of electrotherapy; those who directly use electricity for treatment know of its anti-inflammatory effects. Electronic signal treatment (EST), as an extension of presently available technology, may reasonably have even more anti-inflammatory effects.

EST is a digitally produced alternating current sinusoidal electronic signal with associated harmonics to produce theoretically reasonable and/or scientifically documented physiological effects when applied to the human body. These signals are produced by advanced electronics not possible even 10 to 15 years ago.

The potential long-lasting anti-inflammatory effects of some electrical currents are based on basic physical and biochemical facts listed in the text below, namely that of stimulating and signaling effective and long-lasting anti-inflammatory effects in nerve and muscle cells. The safety of electrotherapeutic treatments in general and EST in particular has been established through extensive clinical use.

The principles of physics have been largely de-emphasized in modern medicine in favor of chemistry. These electrical treatments, a familiar application of physics, thus represent powerful and appropriate elements of physicians' pain care armamentaria in the clinic and possibly for prescription for use at home to improve overall patient care and maintenance of quality of life via low-risk and potentially curative treatments.

Key words: Electroanalgesia, electronic signal treatment (EST), inflammation, anti-inflammatory effects, immune system, neurogenic inflammation, chronic pain, steroids, NSAIDs, osmotic/torsional effect, cAMP, membrane repair and stabilization, pain care/management

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Multiple challenges face the clinician in the effective treatment of inflammation with the current pharmacotherapy (e.g. steroids, NSAIDs, COX-2s). Despite their well-documented short-term efficacy in a wide variety of settings, anti-inflammatory drugs directly interfere with healing (1-7). Even with the short-term benefit, dangers exist with long-term utilization of both classes of drugs. Popular literature refers to over 15,000 deaths annually among patients following the doctor's prescriptions for NSAIDs. In fact, a recent colorful account of the psuedoaddiction of Howard Hughes by Forest Tenant, MD (8) reveals that Hughes died of NSAID induced renal failure.

Inflammation and pain may both play a role in the perpetuation of the other. Sensitization of the pain system can be pro-inflammatory. It is important to understand this relationship in diagnosing, treating, and managing inflammatory pain syndromes (9). When acute inflammation is the starting point and the source, if we can cut the inflammation short, then we can stop chronic pain.

Inflammation has been proposed as the origin of pain (10). Omoigui (10) and others argue that many of our chronic pain syndromes — arthritis, low back pain, fibromyalgia, interstitial cystitis, neuropathic pain, migraine headaches, CRPS — should be reclassified as variations of inflammation-induced pain. Thus the regulation and inhibition of inflammatory mediators which stimulate afferent and efferent neural traffic may be central to the management of these seemingly unrelated syndromes.

There is debate regarding efficacy of epidural and intraarticular steroids for pain management. Many studies and reviews support the short- and long-term use (11,12). However, other studies show mixed results, without long-term efficacy (13). Controlled trials on intraarticular steroids in osteoarthritis, for example, involving over 300 patients, show a short-term benefit that lasts only 1-3 weeks (13).

Steroids may lead to other complications such as steroid-induced osteoporosis, vascular necrosis, and fractures (14). Furthermore, immune disorders secondary to environmental insults contribute to growing inflammation problems. The impact of these physiological challenges is further affected by the inability of physiological repair mechanisms to keep up.

DEFINITION OF INFLAMMATION

Inflammation is a complex process that occurs as a

response to trauma, heat, chemicals, bacteria, or other phenomena, and is mediated by a variety of electrically-charged signal molecules produced locally by mast cells, nerve endings, platelets, and white blood cells (15).

The physiological act of the insulted tissue to repair itself and return to normal happens when naturally occurring bio-chemicals (i.e. arachidonic acid, etc.) are liberated to trigger a response to protect the local tissue and surrounding areas from a specific threat or pathogen (16).

This complete bio-process is essential to the chaotic self-organizing mechanisms of the human bio-system, which allow for normalization of the affected area (17). Exogenous intervention with chemical steroids or NSAIDs may actually restrict this normal bio-system process and possibly produce immediate or long-term undesired side effects to the specific tissue involved, as well as regional or systemic undesired effects (1,18,19).

Inflammation is characterized by

- 1) vasodilatation of the local blood vessels with consequent excess local blood flow,
- 2) increased permeability of the capillaries with leakage of large quantities of fluid into the interstitial spaces,
- 3) clotting of the fluid in the interstitial spaces because of excessive amounts of fibrinogen and other proteins leaking from the capillaries,
- 4) migration of large numbers of granulocytes and monocytes into the tissue, and
- 5) swelling of the tissue cells.

The inflammatory response produces pain, erythema, heat, and edema, all caused by changes in local blood vessels (15). Classes of biochemical mediators of pain include cytokines, neuropeptides, growth factors, and neurotransmitters (10); examples include phospholipase A-2, interleukin 1 (IL-1), IL-6, leukotrienes, prostaglandin E2, nitric oxide (NO), tumor necrosis factor alpha (TNF- α), hydrogen ion (H $+$), NF- κ B, substance P, cGRP, bradykinin, vasoactive intestinal peptide (VIP), nerve growth factor (NGF), and others.

STEROID MECHANISMS OF ACTION IN BLOCKING THE INFLAMMATORY PROCESS

The actions of steroids are generally associated with several principle effects: 1) blocking phospholipase A-2 (PLA-2), a key step in the inflammatory process; 2) membrane stabilizing and consequent analgesic effects, resulting from inhibition of neurotransmission

in c fibers (20); 3) immunosuppression; and 4) anti-edema effects. Other additional mechanisms probably remain undiscovered or not elucidated (21).

Blocking of PLA-2 seems to be the most important effect of steroids. The inflammatory cascade starts when arachidonic acid is released from the disrupted cell membrane. The 2 principle pathways of arachidonic acid metabolism are the 5-lipoxygenase pathway, which produces leukotrienes, and the cyclooxygenase pathway, which produces prostaglandin H₂ (PGH₂). PGH₂ serves as the substrate for 2 enzymatic pathways: one leading to the production of several other prostaglandins, and the second leading to thromboxane. The action of PLA-2 converts arachidonic acid to cyclooxygenase, which, as stated, is blocked by steroids.

The local anesthetic, or membrane stabilizing, effect is considered weak. Steroids are a mainstay for the pharmacologic immunosuppression in organ transplant and auto-immune disease patients, and the anti-edema properties derive from their blocking the anti-inflammatory effects of PLA-2 and other pro-inflammatory agents.

The side effects of steroids have been well described for many years. The practice of the treatment of auto-immune disorders with high dose steroid therapy has carried with it some serious well documented systemic side effects. These are outlined in Table 1 (22).

Serious side effects can also occur even after a single injection of a depot steroid (Table 2). Although these occurrences are relatively uncommon, multiple anecdotal reports suggest that these single dose misadventures do occur more often than expected.

Table 2. *Possible effects of one-shot steroid injection (22)*.

1. Lowered resistance to infections
2. Decreased or altered vision
3. Frequent urination & increased thirst (including Cushing's syndrome)
4. Mental status changes
5. Skin rash and/or hives
6. Local tissue (fat and collagen) necrosis (after single injection, not common, but within the experience of most interventional pain physicians)

Table 1. *Side effects of steroids (22)*

1. Facial flushing (common, but passes quickly)
2. Hyperglycemia (common and can be noted for two weeks after procedure); latent diabetes mellitus often becomes manifest
3. Increased blood pressure (usually high doses; after single injection, not common, but within the experience of most interventional physicians)
4. Hypertension, fluid and sodium retention, edema, worsening of cardiac insufficiency; increases likelihood of MI (unlikely after single injection, cumulative, but not common)
5. Local tissue (fat and collagen) necrosis (after single injection, not common, but within the experience of most interventional physicians)
6. Cushing's syndrome (very common after multiple injections)
7. GI disturbances (common, but all degrees of severity and not necessarily cumulative dose related); ulceration of esophagus, stomach, duodenum possible
8. Increased appetite leading to significant weight gain (causation a problem, but probably common after multiple injections, even if oral forms not used)
9. Immunosuppressant action, particularly if given together with other immunosuppressants such as cyclosporine; fever as a warning symptom often suppressed
10. Osteoporosis with pathological fractures after long-term treatment
11. Possible psychological changes, e.g. depression, personality changes
12. Increased cholesterol (usually high doses; after single injection, not common, but within the experience of most interventional physicians)
13. Avascular necrosis of the hip (would seem to be rare, except from hip joint injections)
14. Steroid myopathy, catabolism (usually after long-term oral use)
15. Dermatologic — wide variety of effects, including, allergic dermatitis, dry scaly skin, ecchymosis and petechiae, erythema, impaired wound-healing, others
16. Epidural lipomatosis (difficult to know; if it occurs, usually subclinical)

NSAID MECHANISMS OF ACTION IN BLOCKING THE INFLAMMATION PROCESS

NSAIDs block inflammation by interfering with the action of COX-1 and COX-2 enzymes. These enzymes facilitate the conversion of arachidonic acid to prostaglandins and thromboxane.

Side effects of NSAIDs include interference with platelets, gastric irritation and bleeding, and renal effects. Since NSAIDs are taken regularly by approximately 33 million Americans, this is a huge epidemiologic challenge. COX-2 inhibitors avoid many of the side effects, but 2 — rofecoxib and valdecoxib — have been pulled off the market because of a higher risk of cardiac dysfunction and death and (in the case of valdecoxib) Stevens-Johnson syndrome. As stated previously in the introduction, various reports estimate that more than 15,000 deaths occur each year as the result of NSAID toxicity. This toxicity is especially noticed in the elderly where NSAID toxicity is more prevalent.

HISTORY OF ELECTRICITY'S USE IN MEDICINE

Electricity has been used for centuries in both diagnostic and therapeutic applications. The 2 earliest recorded uses were in 2750 BC wherein the electrical properties of the Nile catfish were discussed and Hippocrates use of electric fish for medical treatment in 420 BC. In the 1700s European physicians used controlled electrical currents for numerous medical problems including pain and circulatory dysfunction. Ben Franklin documented pain relief using electric currents for a variety of ailments including frozen shoulder. A citation in the early 1900s expounds the benefits of electric current for "...the relief of the superimposed infiltration and chronic inflammation" for an enlarged prostate (23). The same reference goes on to state that "The employment of electricity is amply justified in [cases of pathologically incurable diseases] for the improvement of metabolism, the promotion of comfort and the prolongation of life, but no cure can be expected" (23).

INTRODUCTION TO CONCEPT OF ELECTRIC SIGNAL ENERGY AS A THERAPEUTIC MODALITY

More recently, the most significant development occurred when Becker and Seldon electricaly induced limb regeneration in frogs and rats. In

1982 they reasoned that electromagnetic fields exist that control all aspects of life processes. His studies of extra-neuronal analog electrical morphogenetic fields have eliminated any rational arguments against the importance of bioelectricity for all basic life processes (24). Becker and Seldon asserts in their landmark book that modern scientific knowledge of life's electrical dimension has yielded fundamental insights into pain, inflammation, healing, growth, consciousness, and the nature of life itself (24). The authors now apply these concepts further by showing the influence of EST on inflammation.

An electric field forms around any electrical charge. This means that any other charged object will be attracted (if the polarities are opposite) or repelled (if they are the same) for a certain distance around the first object (24). Electric currents have numerous direct and indirect effects on tissue; these effects will be discussed in more detail in the section "Discussion of the Anti-Inflammatory Effects of EST." Medical/scientific investigations are ongoing and these discoveries could presage a revolution in biology and medicine. According to Becker and Seldon, in the not-to-distant future, physicians may have the ability to control and stimulate bio-system healing at will with the use of exogenous energy fields (24).

THE PRESENT ROLE OF ELECTRICITY IN MEDICINE

It is well known and well accepted that electricity plays an important role in contemporary medicine (25). In diagnostic applications there are a number of valuable devices such as electrocardiography (ECG), electro-encephalography (EEG), electromyography (EMG), nerve conduction velocity (NCV), electrooculography, electroretinography, electronystagmography, electrocochleography, evoked potentials, skin galvanic/impedance tests, current perception threshold (CPT) testing, and sensory nerve conduction testing (Neuralscan).

Therapeutic applications with electrical modalities include a number of medical devices: transcutaneous electric nerve stimulator (TENS), percutaneous electric nerve stimulator (PENS), powered muscle stimulators, interferential current devices (IFC), spinal cord stimulator (SCS), electroconvulsive therapy (ECT), high-voltage galvanic stimulators (HGVS), transcranial electric stimulation, microcurrent stimulators, bone growth stimulators, deep brain probe stimulators, and others.

DEFINING ELECTRONIC SIGNAL THERAPY AND ITS EFFECTS

Sensory and motor neural activity is associated with the action potential, and most chemical interventions become electrical events. We therefore introduce the concept of treating inflammation with specific parameter electronic signal treatment (EST), defined as a digitally produced sinusoidal electronic signal with associated harmonics to produce desired physiological effects. The signals are produced by advanced electronics not available even 10 to 15 years ago.

EST appears to modulate or accelerate the anti-inflammatory process to reduce perpetuation that leads to chronic conditions, especially chronic pain. Concomitant cellular mechanisms support the anti-inflammatory effects of EST; numerous citations exist from the molecular biology, physics, and biochemical literature supporting these ideas. These actions include the oscillo/torsional effect, pH normalization, balancing metabolic concentration differences, cAMP formation and activation (leading to the normalization of cell function), cell membrane repair and stabilization, salutary effects on metabolism, sustained depolarization of the nerve cell membrane (producing nerve block), immune system support, and the obvious macro benefits of increases in blood flow and edema reduction.

The newer systems are EST energy devices which use frequency modulation (FM) alone or amplitude modulation (AM) combined with FM as the basis for signaling the bio-system to initiate complex biochemical responses and actions, e.g., hormone imitative effects, second-messenger formation (cAMP), inhibition of contraction of smooth muscle, vasodilatation, membrane stabilization, and others.

The early systems, or transcutaneous electrical nerve stimulators (TENS), use AM only with frequencies at or between approximately 1–200 Hz. These AM frequencies tend to stimulate and cause neurons to fire. Depending on the rate of nerve impulse firing, a number of physiological mechanisms of action can occur. A simple way of thinking about the differences between EST and TENS is that EST frequency ranges tend to signal, while well known TENS ranges tend to stimulate.

To hypothesize and project how TENS and next-generation EST devices will affect or manipulate the naturally occurring electrical properties of the human bio-system is a daunting and currently impossible task. Although a complete description is beyond the scope

of this paper and our current knowledge base, every journey begins with a single step. A purpose of this paper is to provide this first step and a foundation to pique the interest of basic scientists and clinicians alike.

OVERVIEW OF HOW ELECTRIC SIGNALS MAY BE MORE PHYSIOLOGICALLY EFFECTIVE THAN EXOGENOUS CHEMICALS

The intent of chemical interventions for the treatment of the inflammatory process is to block the process at one or more of the initial steps in the cascade. The authors postulate that EST facilitates the naturally occurring inflammatory process without interfering with the normal inflammatory cascade progression until inflammation is resolved, an idea which at first glance may seem counterintuitive. This facilitation in turn accelerates the anti-inflammatory process to reduce the probability that it becomes drawn out and leads to chronic inflammation. The specific mechanisms of action of the applied electronic signal energy can be effectively used to reduce or modify the undesired symptoms normally present during this inflammatory cascade process. This is illustrated in the box below.

Inflammation → Facilitation → Diffusion → Repair → Normalization

Ten mechanisms are outlined below, which highlight how EST appears to facilitate and accelerate this naturally occurring cascade and eliminate lingering inflammation and its effects on the introduction and proliferation of chronic pain.

The following therapeutically beneficial primary and secondary effects of EST would apply specifically in the anti-inflammatory actions of EST: dilution of toxic substances that cause pain and inflammation; pH normalization; increased tissue metabolism; and improved exchange between intracapillary and interstitial fluid, which in turn results in an improvement of tissue absorption (26). Table 3 lists the primary and secondary effects of electronic signal energy as it applies to its anti-inflammatory activity (27).

Understanding that the human biosystem is primarily electric in nature (24), it is worth mentioning other known physiological effects of electricity (electronic signaling) that will be discussed in future works. These effects or mechanisms of action include: signal

Table 3. *Effects of electronic signal energy as it applies to anti-inflammatory activity (27).*

Primary effects (arising directly from the signal energy)	
i.	cellular oscillo/torsional (ionic movement) effect
ii.	neuron blockade
iii.	imitation of hormone/ligand activity to create an electrical conformation change in the cell membrane G-protein
iv.	sympathetic stimulation (function-imitation)
v.	sympathetic stimulation (function-exhaustion)
Secondary effects (resulting from the primary effect)	
vi.	metabolite movement, dilution & redistribution
vii.	sustained depolarization
viii.	cAMP formation/activation
ix.	cell membrane repair & stabilization
x.	facilitation of metabolism
xi.	vasoconstriction
xii.	vasodilatation
xiii.	immune system support

competition effect via the A-β system (Melzak/Wall's Gate Control Theory), sustained depolarization (Wiedensky Inhibition), neuropeptide release (adrenergic response), increase in dopamine concentration (pain inhibitory transmitter), decrease in NE and 5-HT, acceleration of the re-innervation process, activation of muscle pump, repeated cell membrane depolarization and repolarization activity, muscle training/strengthening, vasomotor imitation, muscle relaxation/spasmolysis (decreasing referred pain and directly decreasing local muscular pain), and accommodation (preventing nerve from "trying to get around" an antidromic block).

SAFETY

The safety of EST has been established throughout extensive use over the past 15 years. Nausea, vomiting, dizziness, etc. are commonly associated with chemical therapies, but are rare with EST. It appears that any EST undesired side effects are minimal and easily avoided.

One notable parameter of importance involving treatment with EST for inflammation processes is dosage, or intensity. Increasing the EST dose too much above the sensory threshold may exacerbate the inflammatory process by directly constricting the small

vessels necessary for moving (diluting) inflammatory mediators. When using the alternating, sequentially generated modulated and unmodulated middle frequencies associated with EST, the electronic signal current sensation felt by the patient decreases as the frequency increases (higher current perception threshold). The clinician asks the patient about his/her sensation of the current as the current is gradually adjusted to the desired therapeutic level. The patient's sensory response often assists in determining the optimum dose, unless a lower dose is otherwise dictated by treatment protocols, which is desired for inflammatory indications.

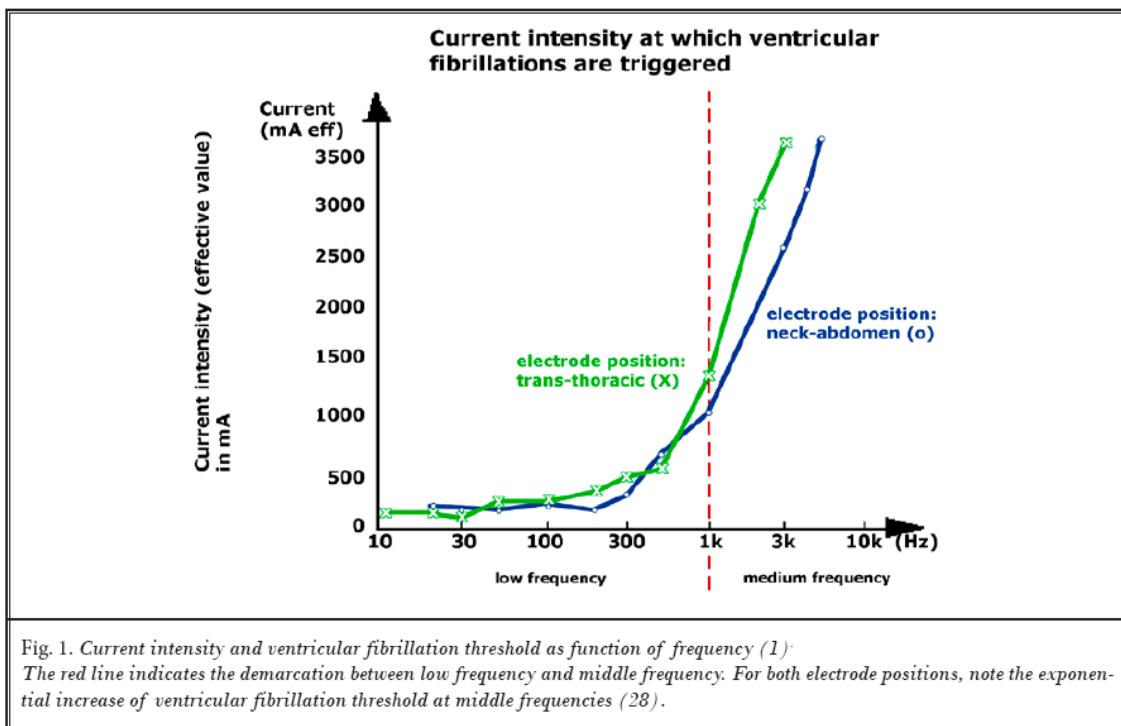
As long as normal sensory responses are maintained with the administration of EST medium frequencies, there is insufficient electrical signal energy delivered to cause tissue damage.

Excess and damaging currents, which could otherwise cause harmful tissue heating, are completely avoided in the conscious patient. There are multiple heat effects on tissue that occur when using much higher frequencies, such as those delivered during Radio Frequency Thermocoagulation (RFTC – 512,000 Hz) treatment: e.g. nerve cell damage occurs over 45° C. and collagen destruction over 67° C. These heat effects are simply not possible when the electrical energy is delivered transcutaneously by current FDA cleared EST generation devices.

The heart is always a concern with electrical devices. The electrophysiological implications of these frequency ranges are shown in Fig. 1 (28). Depending on the frequency and the electrode position (trans-thoracic or neck-abdomen) of applied alternating current, dangerous ventricular fibrillations were induced roughly exponentially with increasing frequency. At frequencies above 4,000 Hz, the risk of interference with cardiac conduction pathways is almost non-existent because the electrical output capabilities of EST devices are much lower than those necessary to trigger ventricular fibrillation. Even if the electrodes are placed across the heart, which is not typically recommended, the electronic signal energy power density field is not high enough to trigger ventricular fibrillation.

DISCUSSION OF THE ANTI-INFLAMMATORY EFFECTS OF EST

The authors have listed below some of the identified mechanisms of action that appear to provide anti-inflammatory effects via EST application. One theoret-



ical mechanism of action (facilitation) listed below is currently postulated by the authors based upon biological responses which may occur in tissues.

- Facilitation
- Oscillo/torsional response
- Enhancement of filtration/diffusion process
- pH normalization
- cAMP formation
- Cell membrane repair
- Influence on metabolism
- Sustained depolarization
- Immune system support
- Increase in blood flow

FACILITATION: ACCELERATION OF NORMAL INFLAMMATORY PROCESS

The inflammation/migration response is initiated by a variety of electrically charged and active signal molecules produced locally by cells or by complement activation. These mediators act on capillary endothelial cells lining the blood vessels, causing them to dilate and become permeable to fluid and proteins (29).

In this paper, we postulate that normally occur-

ring inflammatory processes appear to be facilitated by exogenous administration of alternating polarity electric fields via EST. Specific-parameter EST appears to support the naturally occurring inflammatory process with the following benefits. As the inflammatory metabolic cascade and bio-response is initiated, the oscillo/torsional effect (a direct effect on the cell described in the next section) of the applied electronic signal energy (with imposed rapidly alternating electric polarity-reversals) is delivered to the targeted anatomical inflamed area. The high concentration of electrically charged signal molecules that temporarily exist within the inflamed anatomical treatment field are aggressively moved to and fro in response to the EST energy and concomitant alternating polarity reversals (30,31). Figure 2 illustrates this effect. This enhances the movement, dilution, and redistribution of these charged molecules that are directly linked to pain and inflammation mediators (H ions, etc).

It is hypothesized that, unlike anti-inflammatory drugs, which block the inflammatory mediators or their precursors, electric alternating polarity EST appears to facilitate and support the physiological in-

flammatory process and minimize the time necessary for tissue to repair through a variety of mechanisms which are outlined in the sections which immediately follow.

These mechanisms (e.g. second messenger [cAMP]formation) minimize the normally occurring inflammatory side effects of pain and swelling (32) by initiating repair processes, by balancing chemical concentration differences, and by aggressive filtration and diffusion processes (15).

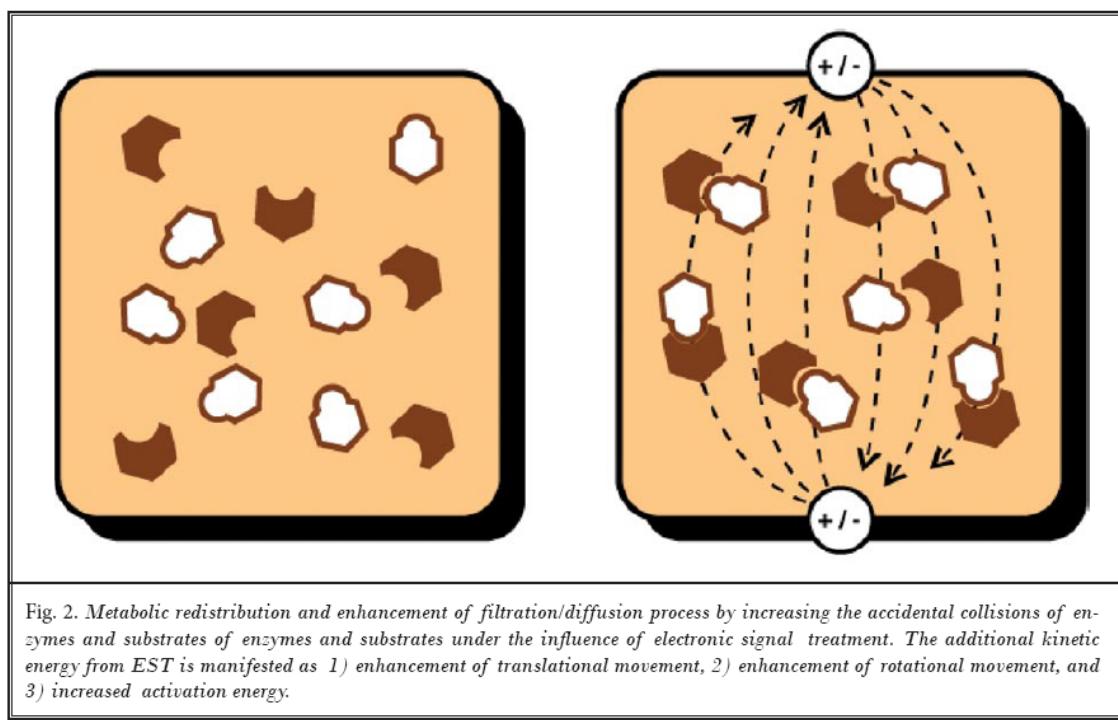
OSCILLO/TORSIONAL RESPONSE (VIBRATION, OSCILLATION, TWISTING AND TURNING EFFECTS)

The oscillo/torsional effect is obtained by an electro-vibratory effect upon the cell itself due to the rapid alternation of electrical polarity charges in response to the higher alternating current signal frequencies used with specific parameter EST energy. The signal's electrical polarity continually reverses from a positive (anodal) charge to a negative (cathodal) at a rate equaling 2 times the delivered EST frequency, i.e. 20,000 PPS

= 40,000 polarity reversals per second. The influence of electrically alternating fields can be expected to enhance the general movement of all charged molecules with additional rotary movement of the charged particles (Fig. 3). This alternating polarity energy increases the probability that specific chemical groups of substrates and enzymes (with normally opposed charges) will meet more readily in the required physiological orientation (33). This effect may be of great importance in enhancing the enzymatic breakdown of pain and inflammatory mediators.

ENHANCEMENT OF FILTRATION/DIFFUSION PROCESSES

EST electrical fields influence enzyme/substrate activity involved in the metabolic process by increasing the kinetic energy of the molecules, an effect which lowers the differences to the required activation energy and transition state (30,32). This increases the probability of important contact and correct orientation connection between enzymes and substrates, which is necessary for the breakdown of pain produc-



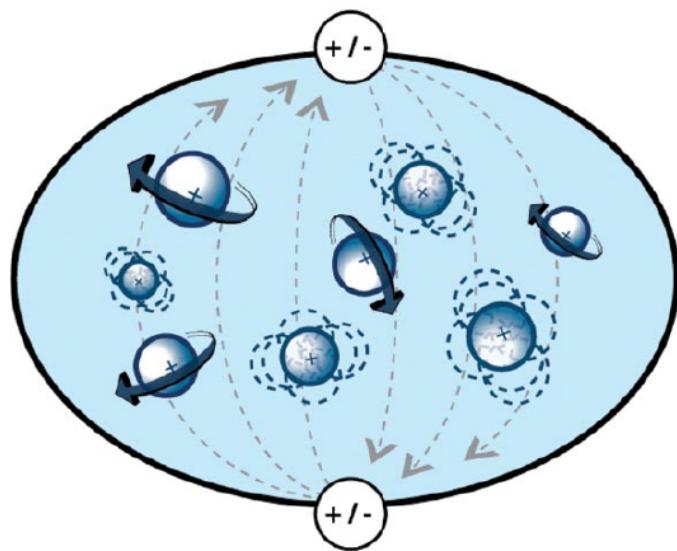


Fig. 3. Influence of an alternating electric field on the orientation and energy of molecules in the cell. This alternating polarity energy increases the probability that specific chemical groups of substrates and enzymes (with normally opposed charges) will chemically react.

ing mediators (33).

The oscillo/torsional response in the cell enhances the naturally occurring filtration and diffusion processes, described in standard physiology texts (34). This effect appears to bring about a balance of metabolic concentration differences where pathologically altered metabolic concentration of substrates and intermediate or final products of metabolism are present in the area of inflammation. This is most likely achieved via the additional kinetic energy supply to the affected region causing an acceleration of the natural filtration/diffusion processes (tissue clearance).

The diffusion/dilution effect and the increase in distribution of the electrically charged substances mediated by EST results in:

- dilution of toxic, pain, and/or inflammation producing substances,
- increase of filtration and diffusion processes (tissue clearance),
- increase in local blood flow,
- improvement of exchange processes of intracellular and extracellular fluids,

- enhanced water electro-osmosis within the tissue,
- and
- improvement of the resorption processes that are important for treating inflammatory conditions and edematous conditions.

Thus EST balances metabolic concentration differences, improves trophism and assists in minimizing undesired tissue inflammation, and normalizes the pH in the local and surrounding tissues.

pH NORMALIZATION (ION EFFECT) AND BALANCING METABOLIC CONCENTRATION DIFFERENCES

The following description is based on common electrochemical principles and the logical extension of that knowledge. The electronic signal energy that is applied will create an electric field with rapidly alternating polarity reversals within that field as described earlier. This electromagnetic field has a direct effect upon the charged molecules positioned within the targeted anatomical field activating a redistribution effect (diffusion) of the charged metabolites that are

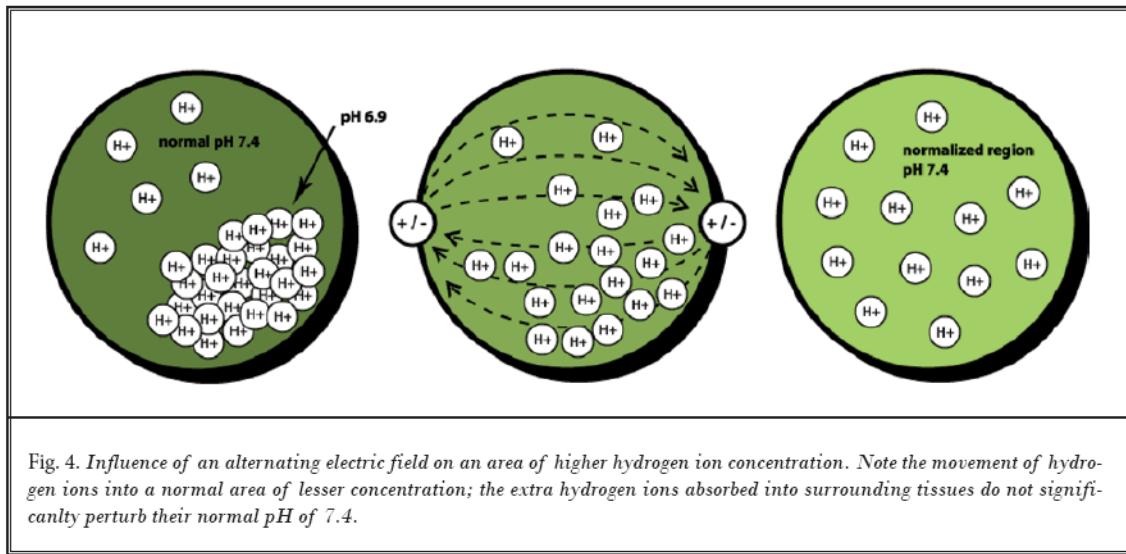


Fig. 4. Influence of an alternating electric field on an area of higher hydrogen ion concentration. Note the movement of hydrogen ions into a normal area of lesser concentration; the extra hydrogen ions absorbed into surrounding tissues do not significantly perturb their normal pH of 7.4.

present in higher concentrations and enhancing the natural filtration process (dilution). The higher concentration of metabolites is electrically moved and head toward other adjacent anatomical areas of less concentration (basic physics law). Hydrogen ions, which are linked to pain and inflammatory mediators (35), are most affected since they are the smallest and most mobile electrically charged ions. This fact has a direct effect by normalizing pH levels in the tissues of the treated anatomical field (balancing metabolic concentration differences). The body functions most normally at pH 7.4, and healing (e.g. anti-inflammatory activity) is optimized.

H⁺ ions are linked directly to pain and inflammation mediators. Figure 4 reveals how middle frequency electric fields via EST decrease H⁺ ions in the inflammatory (concentrated) region. The movement of the H⁺ ions from the inflamed region (pH of 6.9 is used in this example) normalizes the pH in that region, contributing to the healing. The surrounding tissue can easily absorb the extra H⁺ ions without a significant overall drop in pH of the surrounding tissue.

Experimental evidence of activation of the filtration/diffusion process can be readily shown in vitro (36). Figure 5 demonstrates the effects of the oscillo/torsional action and response generated by EST. This effect gives time to the biosystem to overcome the effects of adverse and increased metabolite concentrations.

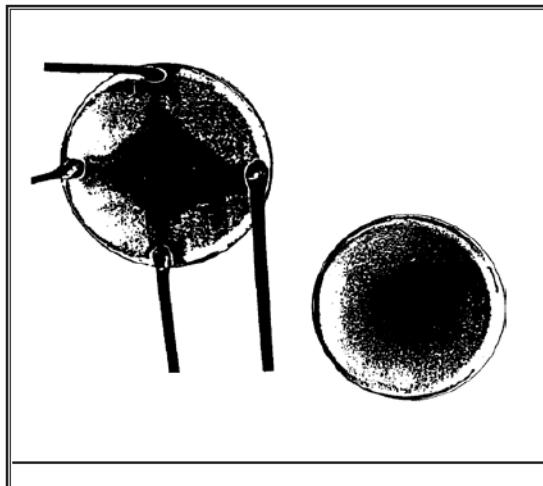


Fig. 5. In vitro view of hydrogen ion (H⁺) concentration (pH) and subsequent movement under the electrical influence of the medium frequency EST fields. Note the attraction toward each of the electrode poles (36).

cAMP FORMATION/ACTIVATION – NORMALIZATION OF CELL FUNCTION

EST energy produces a hormone-like effect by triggering an electrical conformation change to the

cell membrane G protein. This influences adenylate cyclase activity, resulting in the formation of the second messenger cAMP, which may direct cell specific activities, including cellular repair processes. cAMP-induced repair processes are necessary to stabilize the cell membrane and inhibit continued leakage of acids which may contribute to pain and inflammation mediators (29). EST and its effect of a direct electrical conformation change in the cell membrane G protein which ultimately normalizes (increases) cAMP levels may play the most critical role towards normalization of cell function (37).

Multiple references exist to support that cAMP will increase from sustained depolarization of the cell membrane (pharmacological or specific-parameter electrical energy causing sustained cell depolarization) (38). Schwartz (39) states that there are "numerous citations that demonstrate... second messenger formation within the cell at various ion voltage gates when exposed to frequency specific electrical currents." This direct effect of EST serves to increase available cAMP for cell normalization (40,41).

Signaling cAMP leads to the opening of voltage gated channels in efferent c-fibers of pain neurons and the sympathetic nervous system. Vessels will then vasodilate, increasing local circulation, allow incoming nutrients and the washing out of waste products. This cascade will eliminate the primary chemical causes of local pain. In addition, signaling cAMP also leads to decreased afferent c-fiber firing, which in turn decreases epheatic cross firing of afferent A-delta fibers.

CELL MEMBRANE REPAIR/STABILIZATION

Research has shown that electrical field stimulation (EST energy) has a direct effect upon ACTH stimulation, which controls the secretion of cortisol (23). This is the body's own "measured steroid response." Cortisol has 2 basic anti-inflammatory effects: 1) it can block the early stages of the inflammation process or 2) if inflammation has already begun, it causes rapid resolution of the inflammation and increased rapidity of healing. It is believed that cortisol effects assist in the liberation and mobilization of amino acids that can be used to repair the damaged tissues. Endogenous cortisol is much more effective and safe than exogenous cortisol or equivalent because it is "just enough" (15).

The mechanism by which ACTH activates cortisol from adrenocortical cells is a function of cAMP. The principal effect of ACTH on the adrenocortical cells is to activate adenyl cyclase in the cell membrane. This

induces the formation of cAMP in approximately 3 minutes. The cAMP in turn activates the intracellular enzymes that cause the formation of the adrenocortical hormones (32). EST, as shown above, also facilitates the naturally occurring processes necessary for control and mitigation of inflammatory conditions without the usual undesired side effects that accompany the introduction of chemical steroid compounds.

Since second messenger formation (cAMP) directs cell specific activity to membrane repair and stabilization, arachidonic acid release from membrane breakdown is obviously diminished and thus the prostaglandin (inflammation and pain mediator) cascade is attenuated or terminated.

EST frequencies greater than 2,000 Hz have been shown to stimulate utilization of cAMP through sustained depolarization, and cAMP is linked to cell membrane repair (42). Membrane stabilization and repair decreases the supply of arachidonic acid which, in turn, decreases the inflammatory substrate.

INFLUENCE ON METABOLISM

Metabolism means simply the sum total of all the chemical reactions in all of the cells of the body and it can be influenced by EST signal energy in several different ways. The first mechanism is by using lower frequency (0.1 to 200 Hz) electronic signals with specific parameters to stimulate repetitive action impulses (depolarization and repolarization activity) in excitable cells. Repetitive depolarization activity requires a subsequent repolarization response, and this directly challenges the existing metabolic level to increase to meet the demands placed upon the cell.

The second mechanism is by triggering cAMP formation, which activates and initializes metabolism: EST signal energy releases noradrenalin from sympathetic nerve endings resulting in a reaction with receptors on the cell membrane. This triggers cAMP formation from ATP and cAMP activates metabolic processes in the cell.

The third mechanism is by the oscillo/torsional (O/T) effect created by EST signal energy and alternating electric polarity reversals in the target anatomical field: The O/T effect can be expected to achieve facilitation of metabolism through the increase in activation energy. The O/T effect and its electrical effect on the electrically charged enzymes and substrates within the anatomical treatment field also increases the probability that these enzymes and substrates (with specific lock and key components) meet in favorable orientation more often (33).

SUSTAINED DEPOLARIZATION (PLATEAU EFFECT)

Cell membrane sustained depolarization (also termed Wedensky inhibition) occurs with middle frequencies above approximately 2,000 Hz. This leads to nerve cell stabilization as the nerve cell is "locked open." This opening of voltage gated channels induces cellular ion influx/efflux activity. The movement of ions occurs until equilibrium is met, and metabolic activity is now at optimal levels (43).

This effect occurs when higher EST frequencies are applied at a stimulation rate faster than the excitable cell membrane is able to follow (multiple stimulations occur within the absolute refractory period of the membrane). With enough dosage and for as long as the electronic signal is actively deliv-

ered, the membrane will not immediately repolarize, but instead the potential remains on a plateau near the peak of the spike (44). These EST middle frequencies have a direct effect upon voltage dependent gates and the alteration in the membrane physiology is objectively measurable (45). cAMP is utilized and decreased in absolute amounts as it relays the message to open the voltage-gated channels and activates other metabolic activities in the intracellular organelles (46). These EST-induced effects can be described as direct normalization of the cell function, which directly reverses sensitized pain and inflammation feedback circuits and possibly promotes overall healing (25).

As shown in Table 4, the relatively low resistance of nerve and muscle cells favors electrical conduction.

Table 4. *Nomenclature and definitions.*

1. **Voltage:** The tension that results from a difference in the supply of positive and negative charges between two points.
2. **Current:** The movement of charged particles (ions and electrons).
3. **Resistance:** The force that inhibits the flow of charged particles typically measured in Ohms.

a. Nerves	1000 Ω
b. Blood Vessels	1600 Ω
c. Muscle	5000 Ω
d. Bone	160,000 Ω
4. **Impedance:** The property of resistance to alternating current flow, which includes self inductance, capacitance, and ohmic resistance.
5. **Ohm:** The Standard International (SI) unit of electrical resistance. Ohm's law: $V = IR$.
6. **Conductance:** The ease with which an alternating electrical current flows through a substance and is the reciprocal of resistance. $C = 1/R$.
7. **Cell:** In this paper, cell most often refers to the nerve cell, or neuron; however, it may also refer to the muscle cell, which is commonly affected by inflammation. Electricity has its greatest affinity for these 2 types of cells and blood vessels, given their resistance (impedance) values outlined above. These two types of cells also happen to be electrically excitable.
8. **Low Frequencies:** 0.1 – 1,000 Hz
9. **Middle Frequencies:** 1,000 – 100,000 Hz
10. **Metabolic "challenge":** Repeated cell membrane depolarization activity requires subsequent membrane repolarization activity. This requires additional energy production, increasing the metabolism to meet the new demand.
11. **Higher levels of ATP:** Increased requirements for ATP (adenosine triphosphate; the main energy storing molecule) energy levels challenge the metabolism to increase ATP production to meet the demand.
12. **EST:** Electronic signal treatment, a term coined by the authors to characterize the basic mechanism of action.
13. **cAMP:** Cyclic adenosine monophosphate; a second messenger inside most cells.
14. **cGMP:** Cyclic guanidine monophosphate; a second messenger inside most cells.
15. **Specific parameter:** This term is used to identify the requirement for applying a specific electronic signal frequency, a "range" of frequencies or combinations of frequencies to achieve the desired physiological response.
16. **Ephaptic conduction:** This is the excitation of a cell membrane due to its coming into contact with another cell membrane which is excited.

EST works on the excitatory membrane of the muscle cell just as it does on nerve tissue. Higher dose and higher frequency EST signals cause sustained depolarization and the contracture of the smooth muscles of the blood and lymph vessels. This causes a temporary vasoconstriction and an increase in the centripetal transport of the blood and lymph away from the inflammatory, swollen tissue region. Continued application of EST-induced sustained depolarization may result in a block of the release of noradrenalin and therefore vasodilatation (inhibition of smooth muscle contraction). The increase in circulation also favors an earlier resolution of inflammation.

IMMUNE SYSTEM SUPPORT

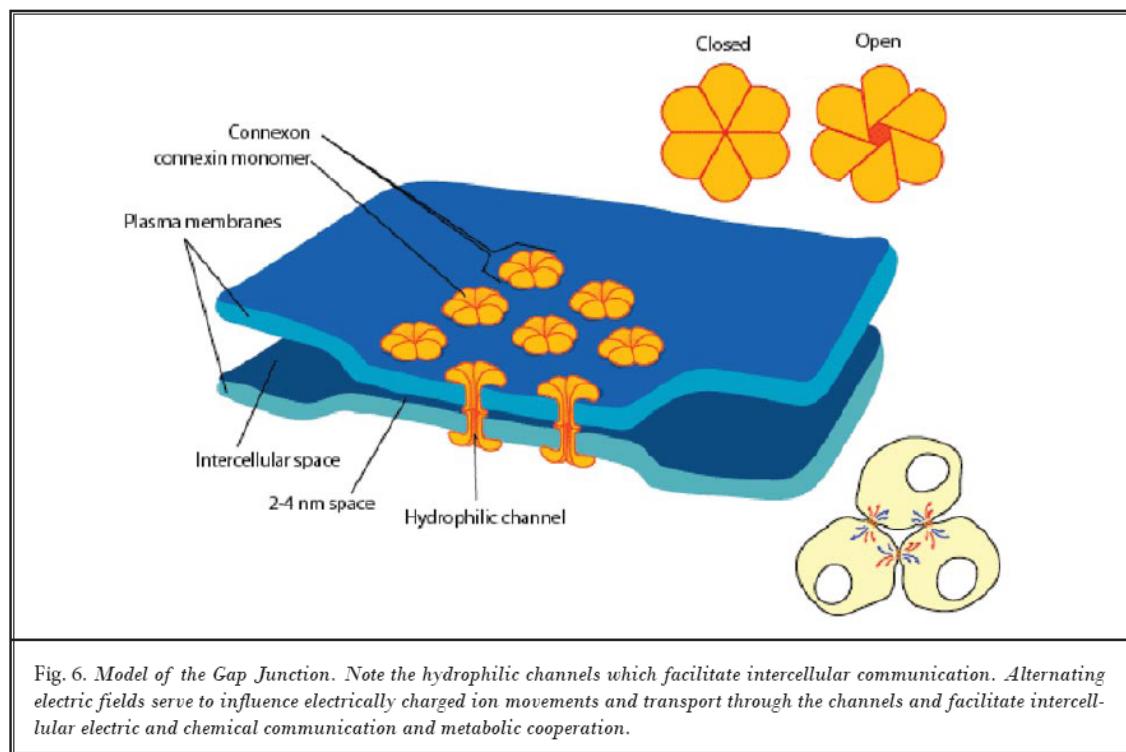
EST appears to improve and support the immune system (unlike chemical steroids) by improving gap junction intercellular communication via EST oscillo/torsional effects.

Gap junctions are protein-lined channels that directly link the cytosol of one cell with another adjacent cell providing a passageway for movement of very small

molecules and ions between the cells (Fig. 6) (47). This allows metabolic coupling or metabolic cooperation between cells. Another important compound transferred from cell to cell through gap junctions is cAMP. The fact that cAMP can transfer from cell to cell through gap junctions means that hormonal stimulation of just one or a few cells can initiate a metabolic reaction in many of them (48). Cell to cell gap junctions are formed quickly when 2 healthy cells come into contact, linking them metabolically as well as electrically.

Gap junctions are also influenced by many other changes in their surroundings, i.e. by changes in the electric membrane potential or the phosphorylation of substances inside the cells produced by hormonal attachment on receptor molecules, which transfer information via signal molecules. This transfer and the common use of small molecules is the basis for intercellular metabolic cooperation and fulfill the precondition for intercellular chemical and electric cooperation.

EST energy influences the electrically charged ion movements through gap junctions by increasing the transport through the cell to cell canals and by facil-



tating intercellular electric and chemical communication and metabolic cooperation. EST energy fields contribute to a functional improvement in tissues which are dysfunctional, e.g., in the healing phase of injured tissue, in degenerative tissue changes, in metabolic conditions, in edema, and in regions of decreased blood supply (49).

In contrast to nature's "measured ACTH and steroid response" described in the section "Cell Membrane Repair/Stabilization," exogenously administered (chemical) steroids may dramatically suppress immune system activity. Therefore, the "appropriate immune response" to the chemical therapy of inflammation is sacrificed.

INCREASE IN BLOOD FLOW/EDEMA REDUCTION (MACRO EFFECT)

The physiological effects (metabolic challenge) of electronic signal energy on motor nerves and muscle stimulation are accomplished by lower frequencies. This effect results in subsequent increased metabolism autoregulatory vascular mechanisms that produce a decrease in peripheral resistance of the vasculature in the stimulated treatment field. These autoregulatory vascular mechanisms are controlled by the end products of metabolism — CO₂, lactate (pH decrease), and adenosine release. ATP consumption is initiated by depolarization of excitable cells and because these cells attempt to immediately repolarize their membrane potential, there is an increased demand for ATP as the source of energy. Higher EST frequency and dosage has a blocking effect (25,27,37) on sympathetic vasoconstrictory nerve fibers resulting in vasodilation within the vasculature innervated by these sympathetic fibers. In this way, blocking afferent c-fibers increases local circulation.

Multiple mechanisms of action apply in the treatment of edematous conditions with EST. When lower frequency parameters are employed at dosage levels above the nerve's firing threshold, the activated nerve stimulation would enhance the centripetal transport of venous blood and lymph via sympathetic stimulation. Higher EST dosage above the muscle contraction threshold would activate the muscle pump response, enhancing also the centripetal flow of blood and lymph. Alternating frequency parameters of applied EST energy are effectively used to assist in the movement of inflammatory mediators and end-products away from the area of inflammation. This effect will also directly lead to the reduction of inflammation.

These physiological effects can be produced in EST-capable devices by programming the use of alternating AM and FM middle frequencies in certain specific-parameter sequences. Edema reduction by EST is so important and complex that a full explanation of current understanding is deferred to a future paper.

TWO APPLICATIONS: NEUROGENIC AND NEURAL INFLAMMATION

The inflammatory response is categorized into 3 types: 1) traumatic — neutrophils and macrophages; 2) immunogenic — lymphocytes and other immune cells; and 3) neurogenic — sprouting nerve cells, degranulating mast cells, altered vascular endothelial cells (1).

Multiple mechanisms for minimizing the effects of the standard inflammatory response by EST have been identified and described. The application of these principles to neurogenic inflammation is now described. Neurogenic inflammation is defined as a process stimulated by chronic severe pain in which the "central nervous system will undergo changes and start generating signals that will maintain and drive the peripheral inflammatory response" (49). This process is a functional as well as an anatomic change. Several pathological processes occur at once: sprouting nerve cells, degranulation of mast cells, and altered vascular endothelial cells. A critical component of this process is the anti-dromic transmission of signals from the dorsal horn cells, which have been stimulated chemically by mast cell release of 5-HT, histamine, and substance P, and electrically by the release of cGRP and substance P to blood vessels resulting in the release of NO, bradykinin, and vasoactive intestinal peptide (VIP) operating directly on nerve endings.

This process is one of the most likely mechanisms for the propagation of chronic pain and is one way of differentiating chronic pain from the acute pain process. An excellent, well-written and easily understood explanation of this important concept can be found in Brookoff's review article (50).

Application of electronic signal treatment can interfere with this pathological process by multiple mechanisms. Cell membrane repair and stabilizing effects of EST are postulated to specifically stabilize mast cells, inhibit their degranulation, and block the release of the algOric pro-inflammatory mediators. This effect, in turn, will serve to block generation of the antidromic transmission originating in the dorsal horn. The sustained depolarization effect directly blocks an-

tidromic propagation from the dorsal horn to the periphery. In addition, the depolarizing effects of EST will block all nerve cell transmission, pro-dromic and anti-dromic. The membrane stabilizing effects of vascular endothelium will also serve to reduce vascular leakage of inflammatory mediators, hydrogen ions, and fluid, and thus block the generation of edema. Also, blocking afferent c-fibers will increase local circulation and further decrease neurogenic inflammation.

Neural inflammation directly results from neural injury. This type of inflammation is directly associated with neuropathic pain, since there are changes in the anatomic structure of the infrastructure. Neural inflammation is very elegantly described in the same article by Brookoff (50) as the result of the interplay of the 3 types of glial cells, all recruited by macrophages, in response to neural injury: 1) microglia; 2) astrocytes; and 3) oligodendrocytes. The microglia are the mediators of the proinflammatory response; their upregulation can lead to the chronic inflammatory state. The astrocytes surround synapses and can send and modify neural signals; and the oligodendrocytes form myelin. According to Brookoff, there is experimental evidence "...implicating neural inflammation as a driver of pain, hyperalgesia, and allodynia" (50).

Just as with neurogenic inflammation, EST can diminish the effects of neural inflammation by minimizing the inflammatory response at multiple points in this cascade. Mitigating the initial inflammatory response by all mechanisms described above would have the overall effect of decreasing the activity of microglia cells to "nip the process in the bud." The EST-induced electrical conformation changes in the cell membrane G-protein as well as other membrane stabilization properties of EST described above, could serve to decrease microglial activity. Likewise, because of the ability of EST to block nerve conduction by causing a sustained depolarized state of the nerve cells, synapses are quiet, non-transmitting, and less likely to be influenced by inflammatory driven astrocyte activities. cAMP formation/activation further will serve to begin the healing process in the nerve cells themselves and minimize the effects of the insult.

The EST effect on both neurogenic and neural inflammation is enhanced by its action on the overall immune function. Important effects include activation of cells of the immune system, sustained depolarization, cAMP formation, facilitation of intracellular communication, an increase in the generation of the natural killer cells (NK) (51), and enhancement of the efficacy

of the activity of the cells of the immune system. This enhanced immune response can serve to manage the development of the neural inflammation response as it does in non-neuronal inflammation.

FINANCIAL RAMIFICATIONS

Health care costs are increasing at an alarming rate (52). Third party payers are becoming increasingly alarmed at the costs of pharmacological treatment and drugs are becoming more expensive per se. Additional costs are iatrogenic — incurred because of complications resulting from the side effects of drugs. Because of the safety profile of EST, there are virtually no expenses associated with side effects.

We also postulate that the safety profile of EST will promote less professional liability exposure. The verification of this statement will only come with the increasing widespread use of EST as an alternative to steroids and NSAIDs.

SUMMARY

We postulate that pharmaceuticals have a tendency to overwhelm biosystems, a very unnatural progression as evidenced by the side effect profiles. EST works through biosystems and their controls. We have presented multiple mechanisms, most documented and one postulated, which demonstrate initial facilitation and then quick resolution of the inflammatory process to prevent it from leading to chronic inflammation and chronic pain. While complex, all concepts above fit together when taken into the context of signaling cAMP; however, the basic signaling mechanism could easily be the oscillo/torsional ionic action on cyclic AMP. Through this and the other mechanisms discussed, cellular derangements are returned to normal in optimum physiological time.

A paradigm shift in our approach, thinking "out of the box," should begin soon, for several reasons. Many patients in chronic pain are simply being under treated for a variety of reasons. Narcotic medications are being diverted in increasing numbers. Most importantly, a recent study on adverse drug events based on the FDA voluntary reporting system has found that the death rate has increased out of proportion to the increase in the number of prescriptions written, and the greatest culprits are pain medications and immune modulating drugs (3). The authors emphasized that these findings "show that the existing system is not adequately protecting patients and underscores the importance of recent reports urging far-reaching

legislative, policy, and institutional changes" (3). One of the purposes in writing this paper is to get the pain management physician to start to think about modifications in his or her therapeutic approach, which might begin by emphasizing the physics approach as well as the pharmacological approach.

The following paragraphs from Potter and Funk (23), written in 1917, still apply and quite nicely summarize the subject: "Success in electrotherapeutics depends on an adequate knowledge of physiology and pathology as related to the human body; on a mastery of the laws that govern electricity [physics]; on the possession of efficient apparatus, the achievement of good technic by practice and the good judgment to apply all these requirements to the best advantage... Electrotherapeutics is not a system to be used to the exclusion of other therapeutic measures, but is a worthy additional unit to any physician's armamentarium...".

CONCLUSION

While we believe that additional studies involving the treatment of inflammatory processes with EST are important, there appears to be enough evidence to encourage the primary or adjuvant use of EST for inflammatory conditions and for the potential replacement of chemical steroids. Finally, we believe that EST and the evidence presented have placed us on a threshold of discovery; it is time to apply this knowledge in the clinical setting. The alternative role of EST (the electric signaling of the cells) will depend on the outcomes of well conducted clinical trials which utilize this reasonable and safe approach.

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APPENDIX B: EFFECTS OF ELECTRO-STIMULATION ON PHYSIOLOGY

Over the past several decades, researchers have studied, experimented and tested their theories of how the body works. As the sphere of knowledge grew and continues to grow many projects centered on the effects of electro-stimulation and electro-acupuncture have been discovered. Below are references for the interested medical technologist to study and from which to add one's own discoveries and theories.

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Beta Endorphin

Electro-acupuncture and Micro-current Signaling for endogenous release of Beta-Endorphin

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Department of Physical Therapy, John G. Rangos, Sr., School of Health Sciences, Duquesne University, Pittsburgh, PA 15282, USA.

Abstract

OBJECTIVE: To determine the effect of transcutaneous neuromuscular electrical stimulation (TNMES) on the degree of microvascular perfusion in autonomically denervated skeletal muscle. **DESIGN:** A completely randomized experimental design was used to compare the effects of TNMES on the degree of microvascular **OBJECTIVE:** perfusion in the tibialis anterior (TA) and extensor digitorum longus (EDL) muscles from autonomically denervated rats (Ch-TES) to

the degree TNMES of microvascular perfusion in the same muscles of untreated controls, rats receiving only TNMES (TES), and rats receiving only autonomic superficial denervation (shams). INTERVENTION: All electrical stimulation treatments were delivered via carbon silicone surface electrodes, and evoked sustained tetanic contraction of (DTA) the TA and EDL muscles. Autonomic denervation was achieved by the application of chlorisondamine. MAIN OUTCOME MEASURES: The degree of muscle, microvascular perfusion was determined for the deep (DTA) and superficial (STA) region of the TA muscle and the EDL muscle TNMES by calculating their perfused microvessel/muscle fiber (PV/F) ratio. RESULTS: The PV/F ratio in the DTA from Ch-TES animals was greater to ($p < \text{or } = .05$) than that in the same muscle from control and sham animals. The PV/F ratios in muscle, the STA and EDL from Ch-TES animals, were not significantly ($p > .05$) different from the PV/F ratio in the muscles respective muscles of shams. CONCLUSIONS: The response of the microvasculature in autonomically denervated skeletal muscle to TNMES that evokes muscle contraction is variable and (2) mechanisms other than autonomic regulation may be involved in this hyperemic response.

Mesh-terms: Analysis of Variance; Animals; Autonomic Denervation; Male; Microcirculation :: physiology; Muscle Contraction :: physiology; Muscle Denervation; Muscle Fibers; Muscle, Skeletal :: anatomy & histology; Muscle, Skeletal :: blood supply; Muscle, Skeletal :: physiology; Rats; Rats, Sprague-Dawley; Support, Non-U.S. Gov't; Support, U.S. Gov't, P.H.S. ; Tetany :: etiology; Transcutaneous Electric Nerve Stimulation :: methods;

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Abstract

Electrotherapy is used clinically according to a variety of protocols and at various intensities with the intent of effecting any number contractions of physiological changes. The purpose of this study was to determine if the increased degree of microvascular perfusion observed following Electrotherapy 2,500 Hz transcutaneous neuromuscular electrical stimulation (TNMES) is dependent on evoked muscle contractions. The tibialis anterior (TA) and extensor digitorum served longus (EDL) muscles from 30 male rats were analyzed. Six animals were untreated and served as controls, while the TA no and EDL muscles of six animals were treated with TNMES at current intensities three times that needed to evoke a rat's minimum visible contraction in the TA (M-TNMES). The remaining animals were treated with gallamine, which effectively blocked neurally mediated muscle of contraction. The TA and EDL muscles of six gallamine-treated rats received no TNMES and served as shams (G-Sham), six received served M-TNMES (GM-TNMES), and six received TNMES at intensities sufficient to produce sustained muscle contraction with a neuromuscular blockade in place a (G-HIS). Perfused microvessels were labeled with fluorescein isothiocyanate-bovine serum albumin. The degree of microvascular perfusion was determined by calculating perfused of microvessel/muscle fiber ratios (PV/F). The mean PV/F ratios of all groups were compared using Fisher's LSD ($\alpha = .05$). When contractions were compared to controls, the PV/F ratios of the TA and EDL muscles in M-TNMES and G-HIS groups showed a significant group ($p < \text{or } = .05$) increase while the G-Sham and GM-TNMES groups were similar to controls.

Mesh-terms: Animals; Male; Microcirculation :: physiology; Muscle Contraction :: physiology; Muscles :: blood supply; Muscles :: physiology; Rats; Rats, Sprague-Dawley; Support, U.S. Gov't, P.H.S. ; Transcutaneous Electric Nerve Stimulation;

F R Clemente, D H Matulionis, K W Barron, D P Currier. Effect of motor neuromuscular electrical stimulation on microvascular perfusion of stimulated rat skeletal muscle. Phys Ther.; 71 (5):397-404; discussion 404-6 2027896 (P,S,G,E,B) May1991

Abstract

The purpose of this study was to determine the effect of neuromuscular electrical stimulation (NMES) (2,500-pps sine wave interrupted at 50 the bps) on the degree of microvascular perfusion in stimulated skeletal muscle. The tibialis anterior (TA) and extensor digitorum longus (EDL) The muscles of 36 male rats were treated with NMES for 30 minutes at current amplitudes sufficient to produce a sustained was muscle contraction (motor NMES). Muscle tissue was removed at, 5, 10, 15, and 30 minutes after NMES. The perfused the vessel/muscle fiber ratio (PV/F) of the stimulated animals at time minutes was greater than that of the unstimulated control on animals. A gradual decrease in the magnitude of the PV/F increase was noted over time. Depending on the muscle's fiber-type at composition, the PV/F values returned to control levels by 10 to 30 minutes after motor NMES. The results indicate (1)removed that motor NMES significantly increases the degree of microvascular perfusion in stimulated rat skeletal muscle and (2) that the increase of degree of perfusion persists for various lengths of time, depending on the fiber-type composition of the muscle. Thus, if responses in an animal model can be used as indicators of similar human responses, then the results of this study suggest that NMES can be used to increase the degree of microvascular perfusion in human skeletal muscle.

Mesh-terms: Animals; Electric Stimulation; Male; Microcirculation :: physiology; Muscle Contraction; Muscles :: blood supply; Rats; Rats, Inbred Strains; Regional Blood Flow; Support, U.S. Gov't, P.H.S. ; Time Factors;

Serotonin

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APPENDIX C: ARTICLES ON ELECTRICAL STIMULATION AND WOUND HEALING

The use of electrical stimulation in wound healing has been widely researched and documented. Following are a selection of research articles attesting to the effectiveness of electrical stimulation to wound healing.

Agren MS, Engel MA, and Mertz PM. (1994) Collagenase during burn wound healing: influence of a hydrogel dressing and pulsed electrical stimulation. Plast. Reconstr. Surg. 94, 518-524. Abstract: Epithelialization of second-degree burn wounds is known to be accelerated by topical treatment with hydrogel dressings and further enhanced by pulsed electrical stimulation compared with no treatment (air exposure). Tissue collagenase has been proposed to be involved during the process of epithelialization. In the present study collagenase levels were examined in partial-thickness burn wounds in the skin of four domestic pigs. Collagenase levels, assayed on postburn days 1 to 10, were substantially reduced in deblistered and air-exposed burn wounds compared with excisional partial-thickness wounds. Early application of hydrogel dressing to the burn wounds was accompanied by elevated collagenase activities and an increased inflammatory reaction in dermis. Addition of pulsed electrical stimulation increased ($p < 0.001$) collagenase levels twofold above those with hydrogel alone during initiation of epithelialization (postburn days 3 and 4). These results suggest that collagenase is closely linked to wound epithelialization.

Akai M, Oda H, Shirasaki Y, and Tateishi T. (1988) Electrical stimulation of ligament healing. An experimental study of the patellar ligament of rabbits. Clin. Orthop. 296-301. Abstract: To examine the effects of direct electric current on ligament healing in rabbits, a full-thickness defect of the patellar ligament was electrically stimulated for time periods of up to seven weeks. The rabbits were randomly assigned to biomechanical and biochemical studies and healing was evaluated by these parameters. Electrical stimulation was shown to restore tensile stiffness in a short period of time and to decrease the relative proportion of Type III collagen more rapidly than in the control group. However, electrical stimulation did not change the collagen content of newly formed tissue. Electricity enhances the repair process of the ligament by changing the ratio of collagen types.

Aro H, Aho AJ, Vaahtoranta K, and Efkors T. (1980) Asymmetric biphasic voltage stimulation of the osteotomized rabbit bone. Acta Orthop. Scand. 51, 711-718. Abstract: An experimental study was performed to determine the effect of electric current on the healing of osteotomies in the antebrachium of the rabbit. Starting with the assumption that the waveform of biphasic asymmetric voltage simulates the asymmetric pattern of stress-induced physiological electrical potentials in normal bone, biphasic asymmetric voltage was applied to the osteotomized radius or ulna. The effects of the electrical stimulation were evaluated by means of X-rays and histological studies. The voltage supplied induced periosteal proliferation whether implanted, insulated electrodes were employed or uninsulated external transfixation pins were used as electrodes. The stimulation had not only osteogenic but also chondrogenic effect. The external callus formation at the osteotomy sites and around the transfixation pins proved to be greater in the stimulated animals than in the controls.

Baker LL, Chambers R, DeMuth SK, and Villar F. (1997) Effects of electrical stimulation on wound healing in patients with diabetic ulcers. Diabetes Care 20, 405-412. Abstract: OBJECTIVE: To evaluate the effects of two stimulation waveforms on healing rates in patients with diabetes and open ulcers. The hypothesis was that stimulus waveforms with minimal polar characteristics would provide significant healing for this patient sample. RESEARCH DESIGN AND METHODS: This was a prospective study that enrolled 80 patients with open ulcers. Patients received stimulation with either an asymmetric biphasic (A) or symmetric biphasic (B) square-wave pulse. Amplitudes were set to activate intact peripheral nerves in the skin. Two other groups received either very low levels of stimulation current (MC), or no electrical stimulation

(C). When combined these groups were referred to as the control group. Treatment was carried out daily until the wound healed, the patient withdrew from the study, or the physician changed the overall wound management program. Average healing rates were calculated from weekly measures of the wound perimeter and were used for statistical comparison through a one-way analysis of variance. **RESULTS:** Stimulation with the A protocol significantly increased the healing rate, enhancing healing by nearly 60% over the control rate of healing. Stimulation with the B protocol did not increase the healing rate when compared with control subjects. **CONCLUSIONS:** Electrical stimulation, given daily with a short pulsed, asymmetric biphasic waveform, was effective for enhancement of healing rates for patients with diabetes and open ulcers.

Becker MH, Lassner F, Dagtekin FZ, Walter GF, and Berger A. (1995) Morphometric changes in free neurovascular latissimus dorsi flaps: an experimental study. Microsurgery 16, 786-792. Abstract: This study was designed to investigate regeneration of reinnervated, free transplanted muscles. We used a rat model, consisting of eight rats per group, in which the latissimus dorsi muscle was transplanted orthotopically and then harvested and evaluated after 2 and 12 weeks. Age-matched control animals were used to oppose non-operated muscles. At date of removal the patency of the vascular anastomoses was checked clinically and histologically. Electrophysiological measurements were also performed and conventional and enzyme histochemical histological slides manufactured. Two weeks after the free neurovascular flap transfer the muscle was not yet innervated, and histologically a dissolved pattern of type I and type IIA muscle fibres was found. The muscle fibres demonstrated a decrease of more than 50% cross-sectional area. After 12 weeks the muscles were reinnervated again; muscle contraction was positive with electrical stimulation and the cross-sectional area had regained 80% of the activity of normal muscle fibers. With enzyme histochemical staining the typical type grouping of reinnervated muscles could be demonstrated.

Biedebach MC. (1989) Accelerated healing of skin ulcers by electrical stimulation and the intracellular physiological mechanisms involved. Acupunct. Electrother. Res. 14, 43-60. Abstract: Evidence is reviewed (8 studies involving 215 clinical patients with ischemic skin ulcers and 7 animal tissue or tissue culture studies) that electrical stimulation of fibroblast cells accelerates the intracellular biosynthesis necessary to form new granulation tissue in a healing wound, and that both a direct local tissue effect and a circulatory improvement occur. A model is presented in which transmembrane currents open voltage-controlled calcium channels in fibroblast cells, causing ATP resynthesis, activation of protein kinase mechanisms to synthesize new cellular protein, and the DNA replication necessary for mitotic cell division. Stimulation efficacy appears to be determined by a number of basic electrical parameters, and judicious waveform control is desirable.

Brown M, McDonnell MK, and Menton DN. (1988) Electrical stimulation effects on cutaneous wound healing in rabbits. A follow-up study. Phys. Ther. 68, 955-960. Abstract: The purpose of this study was to determine the effects of high voltage monophasic pulsed electrical stimulation on wound healing using positive polarity. Forty-four rabbits were assigned to experimental or control groups and followed for four or seven days. We classified the groups as Exp4, Con4, Exp7, and Con7, respectively. Each animal was anesthetized, and a full-thickness incision, 3.5-cm long, was made on its back. After 24 hours, the Exp4 and Exp7 rabbits received high voltage electrical stimulation for two hours twice daily. Wound closure for the Exp4 rabbits (50%) was significantly less than that of the Con4 rabbits (78%). After seven days, however, the Exp7 and Con7 rabbits had similar wound-closure values (80% and 82%, respectively). Tensile-strength values for the control and experimental animals were comparable at both time periods. Histologic examination of the wounds suggested a more rapid rate of epithelialization between the Exp4 and Exp7 rabbits compared with the Con4 and Con7 rabbits. The results of this study are inconclusive, but may indicate that positive-polarity stimulation enhanced wound closure between four and seven days of treatment.

Castillo E, Sumano H, Fortoul TI, and Zepeda A. (1995) The influence of pulsed electrical stimulation on the wound healing of burned rat skin. Arch. Med. Res. 26, 185-189. Abstract: Electrostimulation of wounds caused healing to proceed in a thoroughly organized manner. A trial using rats subjected to second degree burns was conducted to evaluate, under scanning electron microscopy (SEM), the healing capabilities of skin to which an antiseptic (iodine) and referred electrical stimulation were applied. Untreated, unharmed skin was also studied as control. Images obtained using SEM revealed that only the repaired skin of the electrostimulated group had an appearance similar to that of the control skin ($\kappa = 1$), and that the overall appearance of the repaired skin was compatible with a well organized healing process.

Dunn MG, Doillon CJ, Berg RA, Olson RM, and Silver FH. (1988) Wound healing using a collagen matrix: effect of DC electrical stimulation. J. Biomed. Mater. Res. 22, 191-206. Abstract: Rapid fibroblast ingrowth and collagen deposition occurs in a reconstituted type I collagen matrix that is implanted on full-thickness excised animal dermal wounds. The purpose of this study is to evaluate the effects of direct current stimulation on dermal fibroblast ingrowth using carbon fiber electrodes incorporated into a collagen sponge matrix. Preliminary results suggest that fibroblast ingrowth and collagen fiber alignment are increased in collagen sponges stimulated with direct currents between 20 and 100 microA. Maximum fibroblast ingrowth into the collagen sponge is observed near the cathode at a current of 100 microA. These results suggest that electrical stimulation combined with a collagen matrix may be a method to enhance the healing of chronic dermal wounds.

Evans RD, Foltz D, and Foltz K. (2001) Electrical stimulation with bone and wound healing. Clin. Podiatr. Med. Surg. 18, 79-95, vi. Abstract: Electrical stimulation has been used to heal fractures and ulcers and reduce pain through modulation of local body processes. It has been recognized that mechanical forces and bioelectricity have an intimate relationship in influencing the production of bone. Science has developed techniques to affect change in the electrical charge of fractures to positively affect the healing process. Electrical stimulation, through invasive and noninvasive applications, has produced excellent results in the treatment of nonunions and ulcer care. A thorough review of the electrical properties of bone and soft tissue and the influence of electrical stimulation on healing is presented here.

Feedar JA, Kloth LC, and Gentzkow GD. (1991) Chronic dermal ulcer healing enhanced with monophasic pulsed electrical stimulation. Phys. Ther. 71, 639-649. Abstract: The purposes of this randomized, double-blind, multicenter study were to compare healing of chronic dermal ulcers treated with pulsed electrical stimulation with healing of similar wounds treated with sham electrical stimulation and to evaluate patient tolerance to the therapeutic protocol. Forty-seven patients, aged 29 to 91 years, with 50 stage II, III, and IV ulcers were randomly assigned to either a treatment group ($n = 26$) or a control (sham treatment) group ($n = 24$). Treated wounds received 30 minutes of pulsed cathodal electrical stimulation twice daily at a pulse frequency of 128 pulses per second (pps) and a peak amplitude of 29.2 mA if the wound contained necrotic tissue or any drainage that was not serosanguinous. A saline-moistened nontreatment electrode was applied 30.5 cm (12 in) cephalad from the wound. This protocol was continued for 3 days after the wound was debrided or exhibited serosanguinous drainage. Thereafter, the polarity of the treatment electrode on the wound was changed every 3 days until the wound progressed to a stage II classification. The pulse frequency was then reduced to 64 pps, and the treatment electrode polarity was changed daily until the wound was healed. Patients in the control group were treated with the same protocol, except they received sham electrical stimulation. After 4 weeks, wounds in the treatment and control groups were 44% and 67% of their initial size, respectively. The healing rates per week for the treatment and control groups were 14% and 8.25%, respectively. The results of this study indicate that pulsed electrical stimulation has a beneficial effect on healing stage II, III, and IV chronic dermal ulcers.

Gentzkow GD and Miller KH. (1991) Electrical stimulation for dermal wound healing. *Clin. Podiatr. Med. Surg.* **8**, 827-841. Abstract: The investigations of biologic actions (in vitro, animal, and human) demonstrated several effects that help explain why electrical stimulation works. Based on the latest scientific understanding of the wound healing process, one would expect that a therapy that decreases edema, debrides necrotic tissue, attracts neutrophils and macrophages, stimulates receptor sites for growth factors, stimulates growth of fibroblasts and granulation tissue, increases blood flow, stimulates neurite growth, induces epidermal cell migration, prevents postischemic oxygen radical-mediated damage, inhibits bacteria, and reduces numbers of mast cells ought to be beneficial for wound healing. Numerous human and animal efficacy studies confirm that electrical stimulation of the proper charge, density, and total energy causes dramatically improved healing of dermal wounds. As of this writing, no devices have yet been approved by the FDA for use in wound healing, although several devices approved for other indications are being used for this purpose. One device (the Staodyn Dermapulse) has undergone controlled animal and human testing, and an application requesting approval for treating dermal ulcers has been submitted to FDA. Taken together, the efficacy studies and the "mechanism of action" studies provide compelling, scientific evidence that electrical stimulation is safe and effective for promoting the healing of dermal wounds.

Gentzkow GD. (1993) Electrical stimulation to heal dermal wounds. *J. Dermatol. Surg. Oncol.* **19**, 753-758. Abstract: BACKGROUND. Numerous human and animal efficacy studies have demonstrated that electrical stimulation of the correct charge, density and total energy causes dramatically improved healing of dermal wounds. The investigations of biological actions (in vitro, animal, and human) demonstrate several effects that go a long way to explaining why electrical stimulation works. OBJECTIVE. To discuss recent research and advances in electrical stimulation of wound healing. RESULTS. Based on the latest scientific understanding of the wound healing process, one would expect a beneficial outcome from a therapy what decreases edema, debrides necrotic tissue, attracts neutrophils and macrophages, stimulates receptor sites for growth factors, stimulates growth of fibroblasts and granulation tissue, increases blood flow, stimulates neurite growth, induces epidermal cell migration, prevents post- ischemic oxygen radical-mediated damage, inhibits bacteria, and reduces numbers of mast cells. CONCLUSION. Taken together, the efficacy studies and the "mechanism of action" studies provide compelling, scientific evidence that electrical stimulation is safe and effective for promoting the healing of dermal wounds.

Gilcreast DM, Stotts NA, Froelicher ES, Baker LL, and Moss KM. (1998) Effect of electrical stimulation on foot skin perfusion in persons with or at risk for diabetic foot ulcers. *Wound. Repair Regen.* **6**, 434-441.

Khalil Z and Merhi M. (2000) Effects of aging on neurogenic vasodilator responses evoked by transcutaneous electrical nerve stimulation: relevance to wound healing. *J. Gerontol. A Biol. Sci. Med. Sci.* **55**, B257-B263. Abstract: We have previously shown an age-related decline in the modulation of skin vascular reactivity by sensory nerves that correlates with a decline in wound repair efficacy. This study was designed to examine the possibility that improving the functional ability of aged sensory nerves using noninvasive transcutaneous electrical nerve stimulation (TENS) could also accelerate tissue repair. TENS of the sciatic nerve, combined with measuring blood flow responses in the rat hind-footpad using laser Doppler flowmetry, was used to establish the vascular effects. Following TENS (using parameters 20V, 5 Hz for 1 min), similar increases in vascular responses were obtained in both young (13.2+/-0.9 cm²) and old rats (11.6+/-2.3 cm²). In contrast, capsaicin-pretreated rats showed markedly diminished responses. Sympathetic fibers did not appear to modulate these sensory nerve responses. In the second part, a thermal wound was induced (using a CO₂ laser) in the interscapular region of old rats (under anesthesia). In the active treatment group, TENS was applied twice daily for the initial 5 days, and the sham group received inactive TENS. Using the healing endpoint as the time when full wound contraction occurred, the active group required

14.7+/-0.2 days for complete healing, a significant improvement over the sham group (21.8+/-0.3 days). We contend that low-frequency TENS can improve the vascular response of old rats. In addition, wound healing in aged rats can be accelerated by peripheral activation of sensory nerves at low-frequency electrical stimulation parameters.

Kloth LC and Feedar JA. (1988) Acceleration of wound healing with high voltage, monophasic, pulsed current. Phys. Ther. 68, 503-508. Abstract: The purpose of this study was to determine whether high voltage electrical stimulation accelerates the rate of healing of dermal ulcers. Sixteen patients with stage IV decubitis ulcers, ranging in age from 20 to 89 years, participated in the study. The patients were assigned randomly to either a Treatment Group (n = 9) or a Control Group (n = 7). Patients in the Treatment Group received daily electrical stimulation from a commercial high voltage generator. Patients in the Control Group had the electrodes applied daily but received no stimulation. The ulcers of patients in the Treatment Group healed at a mean rate of 44.8% a week and healed 100% over a mean period of 7.3 weeks. The ulcers of patients in the Control Group increased in area an average of 11.6% a week and increased 28.9% over a mean period of 7.4 weeks. The results of this study suggest that high voltage stimulation accelerates the healing rate of stage IV decubitis ulcers in human subjects.

Kloth LC. (1995) Physical modalities in wound management: UVC, therapeutic heating and electrical stimulation. Ostomy. Wound. Manage. 41, 18-4, 26. Abstract: In spite of efforts to create an optimum wound environment for healing, there are times that a wound may not heal, may heal very slowly, or may worsen. In these cases, a series of treatments with an appropriate physical agent can be added to the patient's care plan to augment tissue reparative processes. Three modalities that have received support in the literature for use in wound healing are ultraviolet "C" radiation (UVC), therapeutic heating, and electrical stimulation. Treatment goals for UVC are hyperplasia and enhanced re-epithelialization or desquamation of the leading edge of periucler epidermal cells, granulation tissue formation, sloughing of necrotic tissue, and bactericidal effects. Treatment goals for therapeutic heating are increased blood perfusion with subsequent increased delivery of oxygen to the tissues (avoiding the dessication of wound tissues). The treatment goal for electrical stimulation is to attract negatively or positively charged cells into the wound area, such as neutrophils, macrophages, epidermal cells and fibroblasts that in turn will contribute to wound healing processes by way of their individual cellular activities.

Kloth LC and McCulloch JM. (1996) Promotion of wound healing with electrical stimulation. Adv. Wound. Care 9, 42-45. Abstract: Clinicians involved in the conservative care of chronic wounds have many treatment interventions from which to choose, including debridement/irrigation, dressings, pressure-relieving devices, hyperbaric or topically applied oxygen, whirlpool/pulsed lavage, ultrasound, topical antibiotics, and cytokine growth factors. All except the last two interventions are physical treatments that create a wound-tissue environment conducive to healing. Unfortunately, many chronic wounds heal very slowly, do not heal, or worsen despite the best efforts of caregivers to promote tissue repair. An intervention commonly used to treat chronic wounds, especially by physical therapists, is electrical stimulation (ES). The rationale for use of this method is based on the fact that the human body has an endogenous bioelectric system that enhances healing of bone fractures and soft-tissue wounds. When the body's endogenous bioelectric system fails and cannot contribute to wound repair processes, therapeutic levels of electrical current may be delivered into the wound tissue from an external source. The external current may serve to mimic the failed natural bioelectric currents so that wound healing can proceed. Certain chemotaxic factors found in wound substrates contribute to tissue repair processes by attracting cells into the wound environment. Neutrophil, macrophage, fibroblast, and epidermal cells involved in wound repair carry either a positive or negative charge. When these cells are needed to contribute to autolysis, granulation tissue formation, anti-inflammatory activities, or epidermal resurfacing, ES may facilitate galvanotaxic attraction of these cells into the wound tissue and thereby accelerate healing.

Litke DS and Dahmers LE. (1994) Effects of different levels of direct current on early ligament healing in a rat model. J. Orthop. Res. 12, 683-688. Abstract: Electrical stimulation has been shown to enhance the repair of biological tissues such as bone and tendon. The objective of this study was to determine whether low level direct current enhances the early healing of injured medial collateral ligaments. Eighty-seven rats were divided into three groups on the basis of the level of current delivered. All underwent transection of the medial collateral ligament bilaterally. The experimental medial collateral ligaments received current (which varied by group), while the contralateral medial collateral ligaments (the controls), with identical electrodes, received no current. After 12 days, each ligament was tested biomechanically with use of a hydraulic materials testing machine. Group 1 (8.6 +/- 5.9 microA) showed statistically significant improvements in maximum rupture force, energy absorbed, stiffness, and laxity. The groups that had received lower levels of current did not show significant improvements. In this study, stimulation of 1-20 microA was the most effective level of direct current for the enhancement of early healing of the medial collateral ligament.

Lundeberg TC, Eriksson SV, and Malm M. (1992) Electrical nerve stimulation improves healing of diabetic ulcers. Ann. Plast. Surg. 29, 328-331. Abstract: A controlled study of the effects of electrical nerve stimulation (ENS) was performed in conjunction with a standard treatment for healing chronic diabetic ulcers on 64 patients divided randomly into two groups. All patients received standard treatment (paste-impregnated bandage and a self-adhesive elastic bandage) plus placebo ENS or ENS (alternating constant current; frequency, 80 Hz; pulse width, 1 msec; intensity-evoking strong paresthesias) for 20 minutes twice daily for 12 weeks. Comparison of percentages of healed ulcer area and the number of healed ulcers was made after 2, 4, 6, 8, and 12 weeks. There were significant differences ($p < 0.05$) in both ulcer area and healed ulcers in the ENS group compared with the placebo group after 12 weeks of treatment. The results of the present study support the use of ENS in diabetic ulcers. ENS is easy to apply and can be used by the patient at home following instructions from a medical doctor or a therapist experienced in electrical stimulation and the treatment of ulcers. Additional studies are needed to identify the mechanisms involved in the promotion of ulcer healing with electrical stimulation and to determine the stimulus variables that most efficaciously accelerate tissue repair.

Nessler JP and Mass DP. (1987) Direct-current electrical stimulation of tendon healing in vitro. Clin. Orthop. 303-312. Abstract: The intrinsic capacity of tendons to heal in response to injury has recently been demonstrated by many investigators. Electrical stimulation is often assumed to augment regeneration of various tissues. Using newly developed methods of whole-tendon culture, the authors examined the effect of direct-current electricity on healing in vitro. Deep flexor tendons of rabbits were excised, transected, repaired, and grown in an acellular culture medium for seven, 14, 21, or 42 days. Tendons through which a continuous 7-microAmp current was passed at the repair site were compared with nonstimulated controls. The incorporation of (14C) proline and its conversion to (14C) hydroxyproline was measured at seven days. The mean (14C) proline and (14C) hydroxyproline activities were 91% and 255% greater, respectively, in the stimulated group. The activity was also higher in the stimulated group, by 42 days. Histologic sections showed that intrinsic tenoblastic repair may be enhanced with electrical stimulation in vitro.

Reger SI, Hyodo A, Negami S, Kambic HE, and Sahgal V. (1999) Experimental wound healing with electrical stimulation. Artif. Organs 23, 460-462. Abstract: The effect of alternating current (AC) and direct current (DC) stimulation was studied on experimental pressure ulcer healing in a new monoplegic pig model. The study was conducted in 30 healthy young Hanford minipigs. The rate of wound healing, histology, vascularization, collagen formation, microbiology, perfusion, and the mechanical strength of the healed wounds were studied. Normal pigskin was compared to denervated control and denervated AC and DC stimulated healed skin. Hind limb denervation was by right unilateral extradural rhizotomies from the L2 to S1 nerve roots. Reproducible uniformly controlled Stage III or higher tissue ulcers were created. When

compared to the control wounds, both the AC and DC stimulated wounds showed reduced healing time and increased perfusion in the early phases of healing. DC stimulation reduced the wound area more rapidly than AC, but AC stimulation reduced the wound volume more rapidly than DC. The electrical stimulation did not reduce the strength of the healing wounds below those of the nonstimulated controls. The applied current appears to orient new collagen formation even in the absence of neural influences.

Shandler HS, Weinstein S, and Nathan LE, Jr. (1979) Facilitated healing of osseous lesions in the canine mandible after electrical stimulation. J. Oral Surg. 37, 787-792. Abstract: A study was performed to investigate the effect of electrical stimulation on the repair of osseous lesions in the canine mandible. Results showed considerably more osteoblastic activity on the electrically stimulated side, with maximal growth nearest the negative electrode. Histologic examination showed healing consisted of the production of intramembranous bone, with no evidence of neoplastic changes. The practical uses of electrical stimulation in the practice of oral and maxillofacial surgery are discussed.

Sumano H and Mateos G. (1999) The use of acupuncture-like electrical stimulation for wound healing of lesions unresponsive to conventional treatment. Am. J. Acupunct. 27, 5-14. Abstract: Based on previous experimental evidence suggesting improved healing of wounds treated with electrical stimulation, we conducted a clinical trial with patients seeking alternative medicine after unsuccessful conventional medical treatment. Electricity was delivered in two forms: (1) For wounds with extensive loss of tissue and/or those that had failed to heal spontaneously, electrical stimulation was delivered via subcutaneously inserted needles surrounding the wound edges and applying a dose charge of 0.6 coulombs/cm²/day; (2) in second degree burn injuries, lesions were covered with gauze soaked in a 10% (w/v) sterile saline solution and the same dose of electricity was applied as for (1). Forty-four patients were treated with electrical stimulation of the skin; 34 in group (1) and 10 in group (2). Following electrostimulation in all patients in both groups healing proceeded in a thoroughly organized manner, almost regardless of the severity of the type of wound or burn treated. Advantages and limitations of this technique are discussed.

Taskan I, Ozyazgan I, Tercan M, Kardas HY, Balkanli S, Saraymen R, Zorlu U, and Ozugul Y. (1997) A comparative study of the effect of ultrasound and electrostimulation on wound healing in rats. Plast. Reconstr. Surg. 100, 966-972. Abstract: A comparative study has been carried out to investigate the effects of electrical stimulation and ultrasound on wound healing. Eighty-four female rats were divided into four groups depending on the treatment received. The first group was given electrical stimulation of 300 microA direct current, 30 minutes daily, starting with negative polarity and then changed after 3 days of treatment. Group 2 received sham electrostimulation treatment. The third group received 0.1 W/cm² pulsed ultrasound using the moving applicator technique for 5 minutes a day. Group 4 received sham ultrasound treatment. A total of 7 days of treatment was given to all groups. Histopathologic and biochemical analyses on the fourth and seventh days and wound breaking strength on the twenty-fifth day were performed for all groups. By accelerating the inflammatory phase, electrical stimulation had progressed the proliferative phase of wound healing earlier than ultrasound had done. Both electrical stimulation and ultrasound have positive effects on proliferative phases, but electrical stimulation was superior to ultrasound at the maturation phase. There was no difference between the two experimental groups on the mast cell reduction effect. Although ultrasound treatment may seem to be efficient in terms of time, when the effects of electrical stimulation and ultrasound on wound healing with the methods employed in our study are considered, it is concluded that electrical stimulation is a means of treatment superior to ultrasound in wound healing.

Westerman RA, Carr RW, Delaney CA, Morris MJ, and Roberts RG. (1993) The role of skin nociceptive afferent nerves in blister healing. *Clin. Exp. Neurol.* **30**, 39-60.

Abstract: Because sensory neuropeptides improve survival of critical skin and muscle flaps in rats, skin nociceptive sensory nerve function in blister healing was examined. Sensory nerve ablation by unilateral hind limb denervation or cutaneous axon reflex enhancement by 14 days systemic nicotine treatment (5 mg kg⁻¹ day⁻¹) decreased and increased, respectively, peripheral motor functions of nociceptive (peptidergic) skin nerves. Effects on nociception were measured by a radiant heat tail-flick test. Axon reflex flares were evoked by transdermal iontophoresis of acetylcholine or noxious electrical stimulation under pentobarbitone 40 mg kg⁻¹ anaesthesia. Resultant changes in cutaneous microvascular blood flux were measured non-invasively by laser Doppler flowmetry. In nicotine-treated rats compared with placebo-treated controls, acetylcholine-evoked axon reflex flare was enhanced by 240% ($p < 0.01$) without enhancement of electrically evoked flare. Thus, nicotine-sensitized nociceptors show stimulus specificity in their enhancement of neurogenic flare responses. No significant changes were seen in other endothelial-dependent or smooth muscle-dependent microvascular dilator responses. Nicotine-treated rats had prolonged tail-flick withdrawal latencies to noxious radiant heat stimuli compared with placebo-treated controls ($p < 0.05$), suggesting an antinociceptive or analgesic effect of nicotine-treatment. Neurogenic effects on wound healing rate were assessed by measuring the dimensions of standardized blisters twice daily. The blisters were raised on hind paw glabrous skin using a constant weight and diameter of compressed dry ice pellet applied for 30 secs at constant force. Dry ice blisters raised on the hind paw 14 days post-denervation were significantly slower to heal completely (42 days) than controls (30 days: $P < 0.05$) and the surrounding inflammation was reduced. By contrast, nicotine-treated rats showed more rapid blister healing (25 days) than controls (30 days), seen only in the later phase after day 15. Finally, resting substance P release from blisters, after direct cutaneous nerve stimulation, appears to be enhanced in nicotine-treated rats. Thus nociceptive innervation appears critical for inflammation and rapid healing of blisters in rat skin. The data signal a possible important role for neuropeptides in these processes and question the function of nicotinic receptors on sensory nerves.

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